piccolo® xpress™ Chemistry Analyzer
Operator's Manual

For In-Vitro Diagnostic Use Only

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Section 1 General Information

1.1 Intended Use

The piccolo xpress™ chemistry analyzer provides quantitative in-vitro determinations of clinical chemistry analytes in lithium-heparinized whole blood, heparinized plasma, or serum.

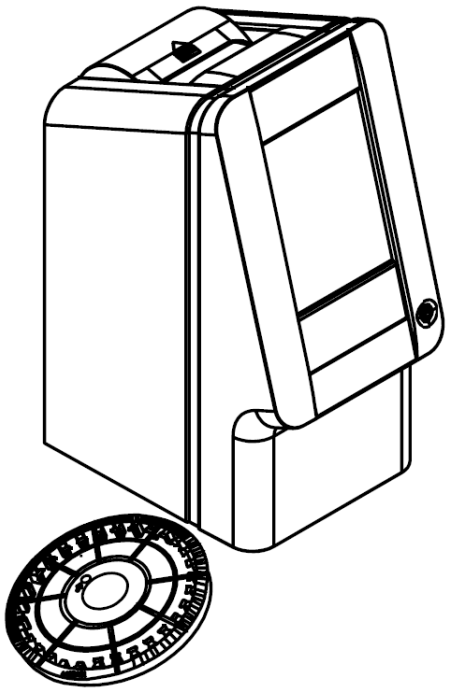
CAUTION: *If the piccolo xpress™ chemistry analyzer is used in any way other than described in this manual, the analyzer may not operate as intended, may produce inaccurate or no results, and may pose a safety hazard.*

Note: *Use only piccolo® reagent discs with the piccolo xpress™ chemistry analyzer.*

1.2 Universal Precautions

Operator health and safety regulations require that Universal Precautions be observed at all times while handling human blood samples or working with the piccolo xpress™ chemistry analyzer in any way. For details, see OSHA 29 CFR Part 1910 ("Occupational Safety and Health Standards"), Standard Number 1910.1030 ("Toxic and Hazardous Substances: Bloodborne Pathogens"), which can be found on the Internet by going to http://www.osha.gov and searching for "1910.1030".

For further guidelines on handling and disposing of hazardous laboratory wastes, refer to "Clinical Laboratory Waste Management; Approved Guideline—Second Edition" (GP5-A2), from the Clinical and Laboratory Standards Institute (formerly NCCLS). This can be found on the Internet at http://www.clsi.org.



1.3 Introduction

The piccolo xpress™ chemistry system is compact and easy to transport. The system consists of a portable analyzer and single-use disposable reagent discs. The analyzer contains the following features and components:

- a variable-speed motor to spin the disc
- a photometer to measure analyte concentrations
- two microprocessors to control testing and analytical functions
- a thermal line printer to print out results
- a VGA color touchscreen for communicating with the analyzer
- optional data functions for more detailed analysis information

Each reagent disc is self-contained clear plastic, 8 cm in diameter and 2 cm thick, and containing an aqueous diluent in its center and dry reagent beads in cuvettes around its edge. All blood separation and sample diluent mixing is performed within the disc itself.

To perform an analysis, the operator needs only to collect a blood sample (lithium-heparinized whole blood or plasma, serum), place the sample in the reagent disc, put the disc into the analyzer drawer on the front of the analyzer, and input patient information. When analysis is finished, the results print automatically.

Results are printed on thermal paper with adhesive backing for inclusion within the patient's medical record. Five USB ports are provided so data can be sent to an external printer, computer, memory stick, or laboratory information systems/electronic medical record systems (LIS/EMR).

The entire analysis requires ~100 µL of sample and is capable of providing results in about 12 minutes.

> ***Note:*** *This manual includes a number of analyzer screens and computer screen captures. The analyzer screens are illustrations only, not exact duplications. All screens represent typical use and installations, and may differ in some minor details from the screens on your system.*

1.4 Technical Support

Abaxis Technical Support personnel are trained to answer questions regarding the operation of the piccolo xpress™ chemistry analyzer. Call Abaxis Technical Support at 800-822-2947.

1.5 Symbols Used in Labeling

The following symbols are found on the back of the analyzer on the piccolo xpress™ label and above the connectors.

Direct current.

Caution. Refer to any accompanying documents.

Biohazard. In accordance with good laboratory practice, consider all material from human sources to be potentially infectious, and handle them with the same precautions used with patient specimens (see Section 1.2).

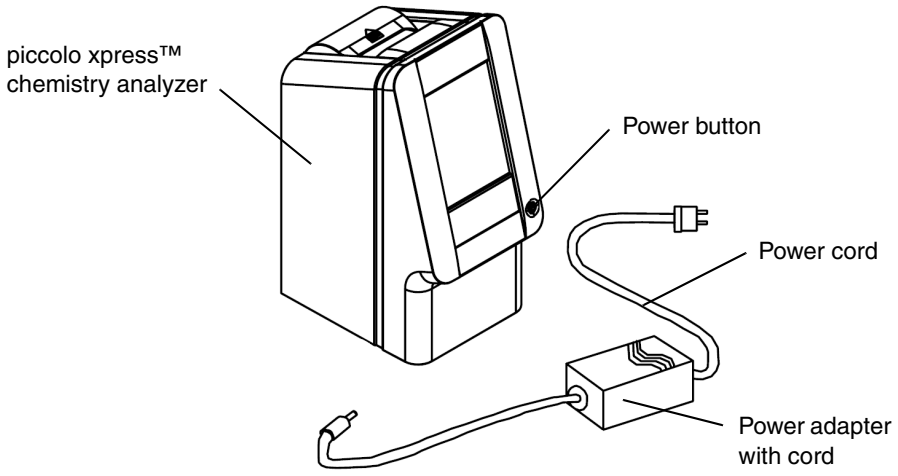
USB connection.

Section 2 Setup and Description

2.1 Unpacking

1. Remove the piccolo xpress™ chemistry analyzer from the shipping carton. Place the analyzer on a level surface that is free of hair, dust, and other contaminants. Do not place the analyzer near a sunny window or any other heat source.

2. Check the components received with the piccolo xpress™ against the following figure to make sure everything required to set up the analyzer is included.



The shipping carton also includes a USB cable, Abaxis Driver CD, piccolo xpress™ Operator's Manual (this manual), Warranty card, and Start-up kit (not shown above).

3. After setup, complete the warranty card and mail it to Abaxis® within 10 days to start the warranty period. Customers are placed on the customer mailing list to receive any information pertaining to the piccolo xpress™ and ancillary products, such as software upgrades.

2.2 Physical & Environmental Specifications

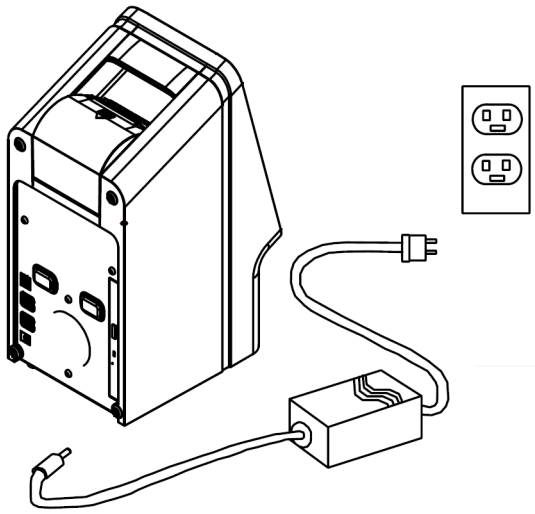
Analyzer dimensions:	*Height:*	*32.4 cm*	*(12.75 inches)*
	Width:	*15.2 cm*	*(6 inches)*
	Depth:	*20.3 cm*	*(8 inches)*
Weight:	*Analyzer:*	*5.1 kg*	*(11.2 pounds)*
	Power adapter:	*0.7 kg*	*(1.6 pounds)*
Mode of operation:	*Continuous*		
Protection against ingress of fluids:	*Ordinary equipment (IPXO)*		
Altitude:	*2000 m (6562 ft)*		
Ambient operating temperature:	*0–40 ºC (32–104 ºF), indoor use*		
Humidity:	*80% relative humidity for temperatures up to 31 ºC (88 ºF), decreasing linearly to 50% relative humidity at 40 ºC (104 ºF)*		
Reaction temperature:	*37 ºC (98.6 ºF)*		
Thermal protection rating:	*70 ºC (158 ºF)*		
Power requirements:	*100–240 volts AC, 50–60 Hz or 15 Volts DC, 5.0A* *Main unit: 1.1 to 0.45 amps, 15 volts DC, 5.0 A*		
Main supply voltage:	*Fluctuations not to exceed ± 10% of the nominal voltage*		
Transient overvoltages:	*Installation Category II in accordance with UL 61010A-1 first edition Annex J*		
Pollution:	*Degree 2 in accordance with IEC 664*		

2.3 Setup

1. Set up the piccolo xpress™ on a surface as follows:

   - Level.
   - Free of vibration and sudden jolts.
   - Free of hair, dust, and other contaminants.
   - Located in an ambient operating temperature of 15–32 ºC (59–90 ºF).
   - Away from sunny windows and all other potential heat sources.
   - At least six inches from any wall to provide adequate ventilation and access to the power connection and USB ports.

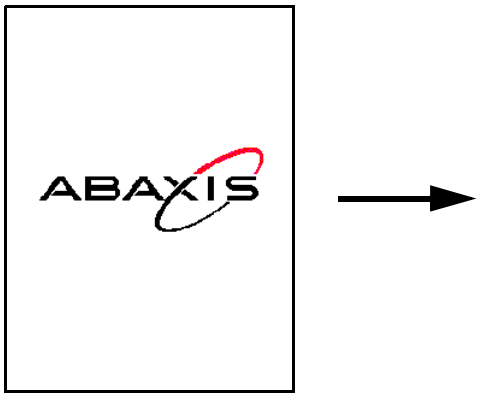
2. Plug the power jack into the analyzer, then plug the detachable power supply cord into the power adapter and into a grounded electrical outlet.



CAUTION: *To prevent power surges or drain, DO NOT plug the analyzer into the same circuit as a centrifuge or any other high-current device. Abaxis also recommends using a surge protector of the same type used for computers.*

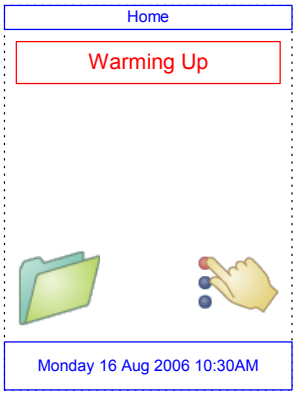
3. Press the Power button to turn on the analyzer.

The display then shows the following:

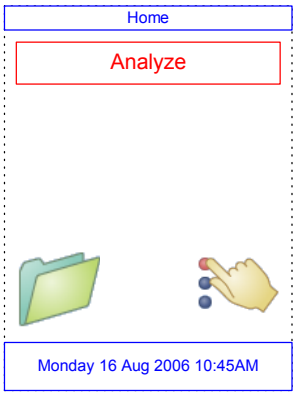


Note: *If the display is blank (shows no message), remove the plug from the power adapter, then re-insert the plug and press firmly to make sure it seats correctly.*

During the warming period, the display reads as shown:



4. After passing the self test and reaching operating temperature, the analyzer is ready to run the first reagent disc, and displays "Analyze":



   See Section 6.2, "Quality Control Features" for details about the analyzer self test. The analyzer may require additional time for the heaters to warm the analyzer to operating temperature.

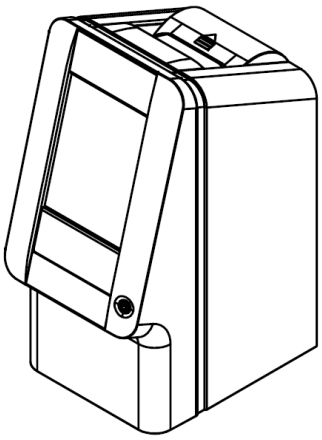
5. Check the analyzer date and time to ensure they are correct. Refer to Section 4.7, "Changing Date and Time" for directions.

6. The analyzer can be connected to an external computer or printer to transmit or print patient and control results. See Section 10, "Connecting a Computer/Printer" for instructions.

7. Reference ranges are preset when the analyzer is shipped from the factory. The range values can be changed using the Customizing Reference Range feature described in Section 4.2.

2.4 piccolo xpress™ System Description

The piccolo chemistry system consists of a portable analyzer and disposable single-use reagent discs. Each reagent disc contains all the reagents needed to perform a panel of tests on a single sample. *Be sure to become familiar with the system before running samples.*



The piccolo xpress™ analyzer uses centrifugal and capillary forces to process heparinized whole blood samples and distribute diluted plasma to the reaction chambers (cuvettes) in the reagent disc. Serum and heparinized plasma samples are processed in a similar manner. The analyzer optically measures the chemical reactions and calculates analyte concentrations from these measurements and from encoded calibration data contained on the bar code ring on the reagent disc.

Results are stored in memory, and can be printed using the built-in thermal printer or downloaded to an external personal computer for data management.

The touchscreen display provides easy communication with the analyzer. The touchscreen shows procedural instructions, indicates the status of the analyzer, and presents any error messages. For details, see Section 2.5.

The reagent disc drawer slides out from the front of the analyzer, and transports the reagent disc (see Section 2.6) into the analyzer and automatically positions it for analysis.

The analyzer prints results on adhesive-backed thermal paper tape, through its internal printer.

The external power adapter changes the electrical outlet voltage to DC voltage required by the analyzer. Two power supply cords are provided: one cord is connected to the power adapter and plugs into the back of the analyze, while the other connects the power adapter to a surge protector designed for use with a computer.

The analyzer has several USB connectors. Use the top USB connector for connecting to an external computer (see Section 10, "Connecting a Computer/Printer" for details).

The analyzer is easy to carry using the recessed handle incorporated into the top of the unit.

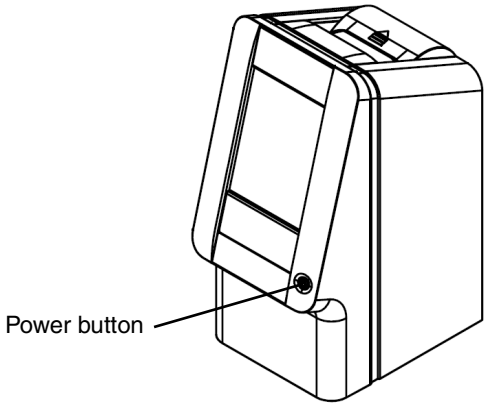
2.5 Touchscreen and Front Panel

You'll use the analyzer's touchscreen display to operate the analyzer.

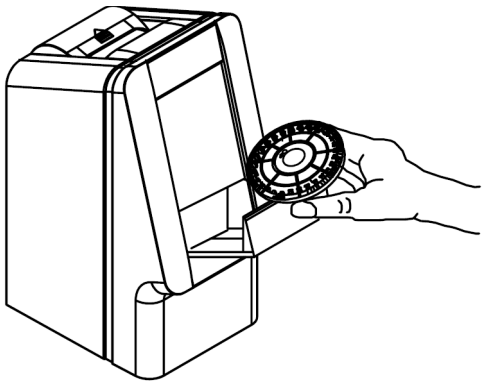
- Use the ten numbers on the touchscreen to input patient information.
- The left and right arrow touchscreen keys move the display cursor forward or backward to change a number on the display. The right arrow key (▶) functions as a dash (–) when entering a patient identification number. The left arrow key (◀) functions as a backspace.
- Use the up (▲) and down (▼) arrow keys to scroll through a displayed list of items, or to increase or decrease a displayed value.
- Operating functions are available through various icons on the touchscreen, as well as specific keys that appear on the touchscreen according to the actions performed.
- Press **Back** on the touchscreen to cancel a choice and return to the previous screen, or to move backward through a series of screens.

Turn the analyzer's power on and off by pressing the Power button on the front of the instrument.

(This button can only turn the power turned off if the drawer is closed and there is no disc in the analyzer.)



The drawer opens or closes by pressing **Analyze** or **CLOSE** on the touchscreen. Closing a drawer containing a reagent disc initiates an analysis.

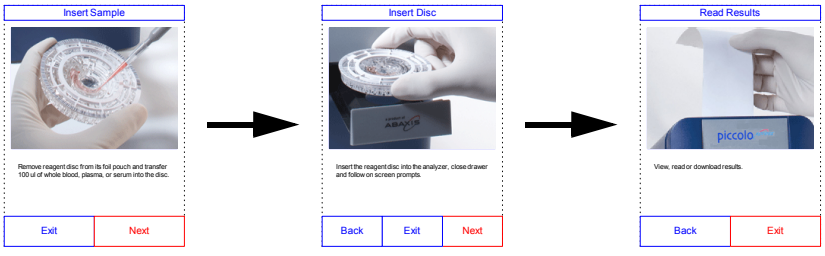


Results for previously analyzed samples can be accessed using the Recall function — see "Recalling Results" on page 5-1 for instructions.

Information Icons

A number of the piccolo xpress™ touchscreen displays include an information icon that you can press to get additional information about the procedure you're performing.

For example, in the screen that appears when you load a disc, you can press to view screens outlining the basic analysis procedure:


Insert Sample
Remove reagent disc from its foil pouch and transfer 100 ul of whole blood, plasma, or serum into the disc.
Exit
Next
Insert Disc
Insert the reagent disc into the analyzer, close drawer and follow on screen prompts.
Back
Exit
Next
Read Results
View, read or download results.
Back
Exit

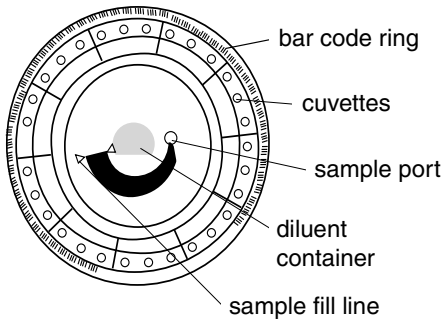
Press **Next** and **Back** to move through the information screens, and **Exit** to close them.

2.6 Reagent Discs

Disc structure and function

In the piccolo® system, all chemistry reactions are performed inside clear plastic reagent discs, 8 cm in diameter and 2 cm thick, specially designed to perform all the steps required to convert a few drops of whole blood, plasma, or serum into a panel of test results. Each disc contains all the components and reagents needed to perform one or more tests on a single sample.

A total of 30 **cuvettes** are located around the periphery:



- four system cuvettes contain QC reagent beads for instrument and chemistry quality control
- a minimum and a maximum absorbance cuvette are used to calibrate the spectrophotometer
- a specially designed cuvette detects whether sample volume was sufficient
- a cuvette verifies that sufficient diluted sample was delivered to the reaction cuvettes
- an empty cuvette captures excess fluids
- 21 cuvettes contain test-specific lyophilized reagent beads.

The **bar code ring** attached to the top of the reagent disc contains calibration data for the specific chemistries in the disc. It also contains the disc identification code, lot number, and expiration date. The analyzer automatically checks the code and rejects any expired disc. The bar code ring also protects the optical surfaces of the cuvette from fingerprints and debris, and helps minimize contamination of the analyzer by capturing small drops of blood that may be on the disc surface.

The **sample port**, marked by an arrow pointing to a molded circle on the disc's upper surface, provides access to the **sample chamber**. When sufficient sample has been loaded into the sample chamber, the **sample fill line** forms between two molded arrows on the disc surface.

A sample **diluent** is sealed in a container inside the center of the disc. At the beginning of the reaction cycle, the analyzer opens this container and releases the diluent.

The analyzer separates a lithium-heparinized whole blood sample by centrifugation inside the disc. Plasma and serum samples are unaffected. Precisely measured quantities of sample and diluent are delivered to the **mixing chamber**. Centrifugal and capillary forces then deliver the diluted sample to the cuvettes, where it dissolves the reagent beads and initiates the chemical reactions. Reaction products in the cuvettes are then measured photometrically.

Disc Storage and Handling

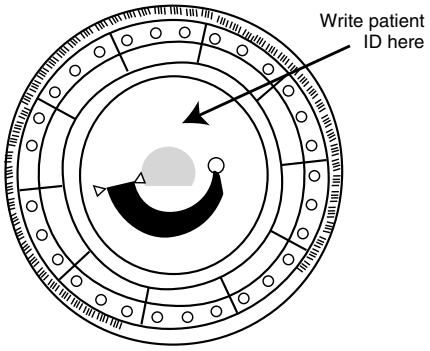
CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. Do not use a disk that has been dropped.*

Inspect ***every*** *reagent disc for damage before use.* ***Never use a damaged disc.***

- Store each reagent disc as described on its label. This keeps the disc's reagents stable until the expiration date printed on the disc's foil pouch and encoded in its bar code ring. The analyzer automatically rejects any expired disc.
- Discs can be used directly from the refrigerator (stored at 2–8 °C) without warming.
- A disc can remain in its sealed pouch at room temperature for a cumulative period of 48 hours. Longer time at room temperature can cause suppression of chemistries and disc cancellations.
- Do not expose discs — in or out of their foil pouches — to direct sunlight or to temperatures above 32 °C (90 °F).
- Inspect the unopened foil pouch for tears and punctures. A torn or damaged pouch can allow moisture to reach the disc and reduce reagent performance.
- Open the disc pouch at the notch on the top right edge of the package.

Note: *You must use the disc* ***within 20 minutes*** *of opening its pouch.*

- Once the pouch is opened, do not place the disc back in the refrigerator for later use.
- Keep discs clean. Handle them only by their edges to avoid smudges on the optical surfaces. Use a lint-free tissue to remove any spilled blood from disc surfaces.
- **Optional:** Write the patient identification number on the disc surface in the space shown at right. Do not write anywhere else on the disc, or on the bar code ring.
- Hold reagent discs flat after introducing the sample or control to avoid spillage.



WARNING: ***BIOHAZARD: Used reagent discs contain body fluids. Follow good laboratory working practices. Handle all used discs as if they are contaminated with hepatitis or other infectious diseases. Check with the appropriate state agency regarding disposal regulations. For more information, see*** ***Section 1.2, "Universal Precautions," on page 1-1******.***

2.7 Ancillary Products

To order consumables or supplies such as reagent discs, pipettes, tips, printer paper, or control samples, contact your authorized distributor, or call Abaxis Customer Service at 800-822-2947.

Section 3

Testing and Results

3.1 Sample Requirements

- The piccolo xpress™ chemistry analyzer accepts lithium-heparinized whole blood, plasma, or serum samples.
- Lithium heparin is the only anticoagulant recommended for use with the piccolo xpress™.

Note: *When collecting the sample in lithium heparin collection tubes, fill the tube at least half-way so the anticoagulant does not become too concentrated in the sample.*

- **If using CLIA '88 Waived reagent discs:** only lithium-heparinized whole blood can be used as a sample.
- **If performing a Basic Metabolic Panel Plus:** only lithium-heparinized plasma or serum can be used as a sample. Heparinized whole blood cannot be used.
- A sample size of 90–120 µL is required.
- Whole blood must be analyzed within 60 minutes of collection, or separated into plasma or serum.
- To prevent hemolysis, do not refrigerate or shake whole blood.
- If not analyzed immediately, plasma or serum can be stored at room temperature for no longer than 5 hours after centrifugation. If storage for more than 5 hours is required, refrigerate the sample in the stoppered tube at 2–8 °C (36–46 °F) for no longer than 48 hours, or store it at –10 °C for up to 5 weeks in a freezer with no self-defrost cycle. Under these conditions, there will be no clinically important changes in most analyte concentrations.
- For accurate interpretation of glucose results, the patient should fast for at least 12 hours before the sample is collected.

WARNING: ***Operator health and safety regulations require that Universal Precautions be observed at all times while handling human blood samples or working with the piccolo xpress™ chemistry analyzer in any way.***

For details, please refer to OSHA 29 CFR Part 1910 ("Occupational Safety and Health Standards"), Standard Number 1910.1030 ("Toxic and Hazardous Substances: Bloodborne Pathogens"), which can be found on the Internet by going to this address:

http://www.osha.gov

and searching for "1910.1030".

Note: *Operators must also be aware of state and local OSHA biohazard regulations that may specify requirements in addition to the federal regulations, and must also ensure compliance procedures are in place.*

3.2 Preparing the Reagent Disc

- Refer to Section 2.6, "Reagent Discs," on page 2-7 for complete information about piccolo® reagent discs, including handling instructions. Make sure you are thoroughly familiar with this information before beginning to use the analyzer.
- Refer to Section 3.1, "Sample Requirements," on page 3-1 for sample handling and storage requirements.

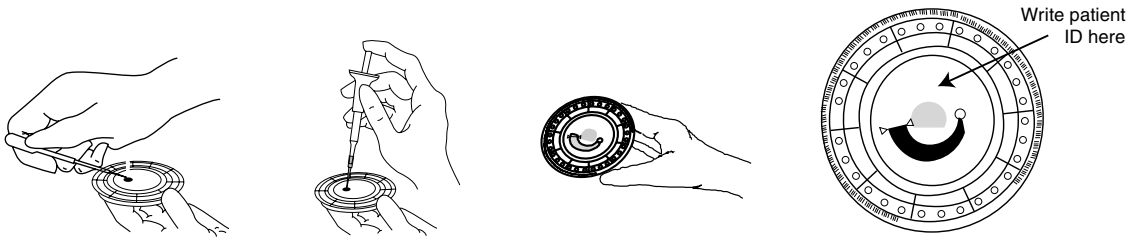
Note: *Analysis must begin immediately (no more than 10 minutes) after dispensing the sample into the reagent disc.*

CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. Do not use a disk that has been dropped.*

Inspect ***every*** *reagent disc for damage before use.* ***Never use a damaged disc.***

Step 1 — Dispense the Sample

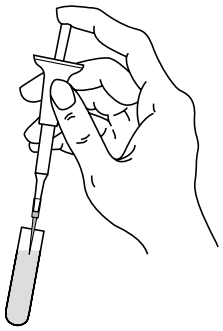
Use a micropipette (one is included with the piccolo xpress™) or other transfer device to dispense approximately 100 µL of sample into the disc via the sample chamber.



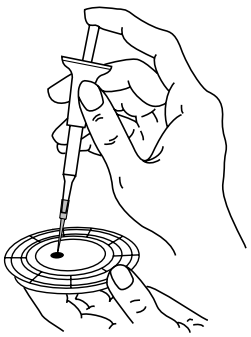
CAUTION: ***Wear powder-free gloves while handling reagent discs or operating the analyzer. Powder can disrupt the analyzer's optical components.***

a. Fill the sample chamber.

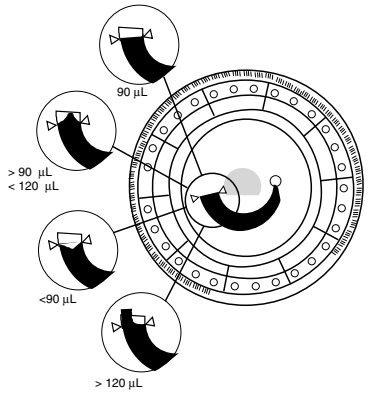
1. Using the Piccolo 100 µl volume pipette, firmly attach a new tip to the end of the pipette. DO NOT touch the tip (this could cause a false elevation of amylase).
2. With your index finger or thumb, push the pipette button to the stop position and hold it down for sample pickup.
3. Immerse the tip 2–3 mm below the surface of the sample, as shown at right.



4. **SLOWLY** release the button to pick up the sample. Pause, then remove the pipette from the sample tube.
5. Make sure there are no air bubbles or air gaps in the pipette tip.
6. Place the pipette tip into the disc's sample chamber, and tilt the disc to 45° with the sample port above the fill line, so that the entire sample flows into the sample chamber. The tip should touch the sample chamber, as shown at right.



7. Push the plunger down with a slow, continuous motion. Take care not to overfill the sample chamber. A 90 µL sample will fill the sample chamber and form a line between the two arrows molded on the disc. More than 120 µL of sample will overfill the chamber.



8. Discard the pipette tip into a biohazard container.

9. Clean the reagent disc. Use a lint-free tissue to remove any sample spilled on the outside of the disc, taking care that the tissue does not withdraw any sample from the sample port. Dispose of the tissue in a biohazard container.

b. Optional: Label the disc.

Write the patient ID on the disc surface in the space shown on page 3-3. Do not write anywhere else on the disc or on the bar code ring.

c. Carry the prepared disc to the analyzer.

Hold the disc by its edges in a flat position.

CAUTION: *Do not remove the sample and try to reintroduce it into the disc.*

3.3 Running a Patient Sample

This section includes detailed, step-by-step instructions for performing analyses using the piccolo xpress™.

Note: *The analyzer includes a number of optional data functions that can be used to enter more detailed information about samples.*

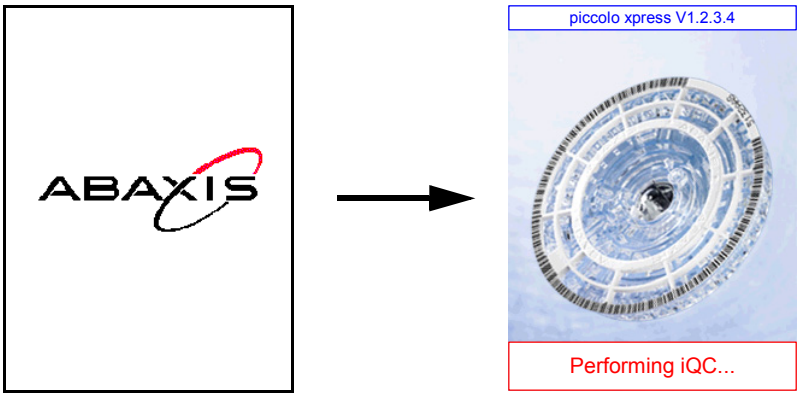
In this manual, the steps for these optional functions are marked with the Advanced Setting icon:

The screens for these optional functions appear on the analyzer only if the functions are enabled. ***If a screen shown in a procedure step in this manual does not appear on the analyzer screen, skip that step.*** *(See "Using Optional Data Functions" on page 4-33 for details about these functions.)*

1. Turn on the analyzer by pressing the Power button on the front of the analyzer. *Do this before removing reagent discs from the refrigerator.*

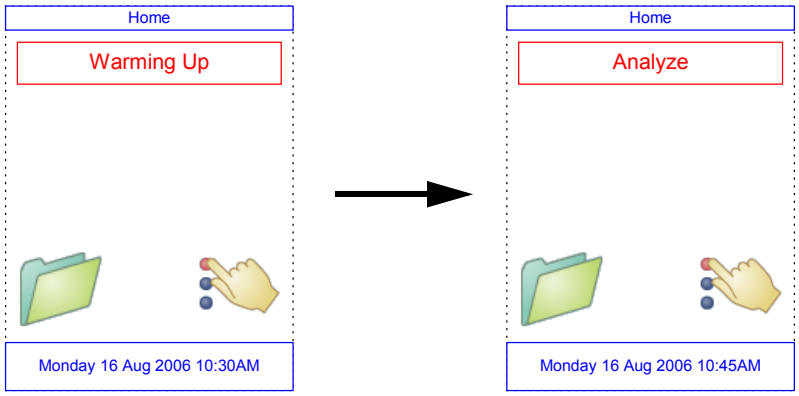
The analyzer starts up, then performs a self test.

See Section 6.2, "Quality Control Features" for information about the analyzer self test.



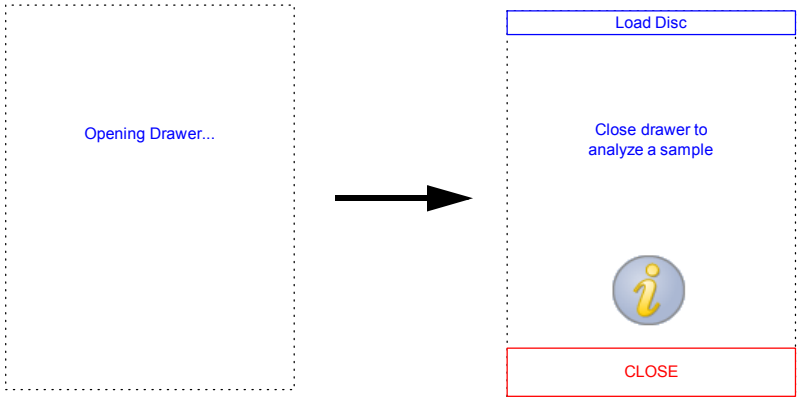
If the analyzer needs time to warm the disc chamber to operating temperature, the display shows "Warming Up."

When the analyzer reaches operating temperature, it displays "Analyze" on the Home screen, as shown at right.



2. Press **Analyze** on the touchscreen to open the disc drawer.

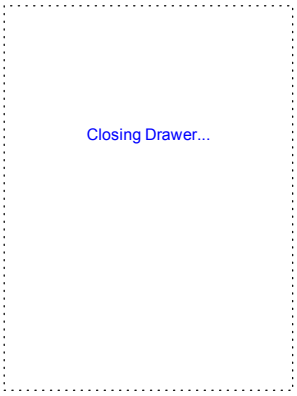
The following messages are then displayed:



Note: *You can press the information icon* *in the Load Disc screen to see help screens outlining the basic analysis procedure. Press* ***Next*** *and* ***Back*** *to move through the help screens, and* ***Exit*** *to close them.*

3. Place the disc in the recessed area in the drawer.

4. Press **CLOSE** on the touchscreen. The analyzer then closes the drawer.



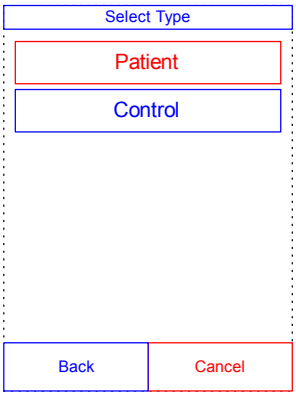
5. **Optional:** Enter the operator ID using the touchscreen, then press **Done**.

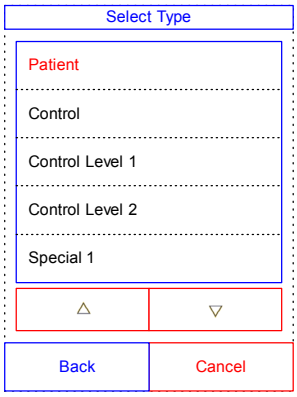
The operator ID is a number of up to 14 digits.

The right arrow key (▶) functions as a dash (–), and the left arrow key (◀) functions as a backspace.

6. Select the sample type from those shown in the display.

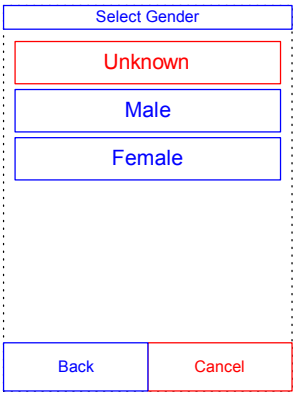
The figure at left shows the default selections: **Patient** and **Control**. Your actual choices will depend on how the analyzer is configured — see "Using Optional Data Functions" on page 4-33.



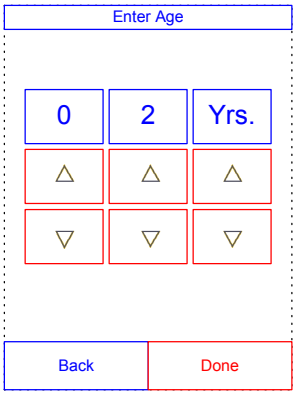


Note: *The correct sample Type is necessary for results to be interpreted correctly.*

7. **Optional:** Select the patient's gender.



8. **Optional:** Enter the patient's age using the up (▲) and down (▼) arrow keys, and adjust the units if needed. Then press **Done**.

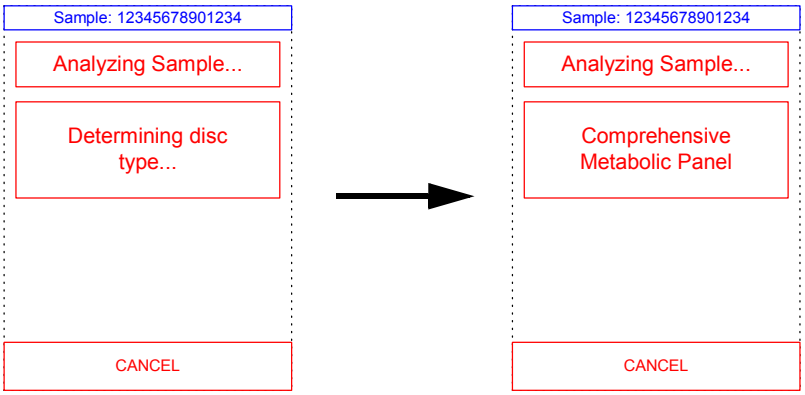


9. Enter an ID number for the sample (up to 14 characters), then press **Done**.

   The right arrow key (▶) functions as a dash (–), and the left arrow key (◀) functions as a backspace.

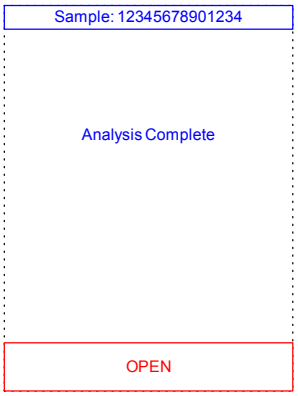
10. **Optional:** Enter an alternate ID (up to 14 characters), then press **Done**.

11. The analyzer then checks the disc type, and begins processing the sample.



Note: *If the disc is found to be of an incorrect type or expired, an error message appears. Repeat the analysis with another disc of the correct type.*

12. When the sample is finished processing, the analyzer stores the results and shows that the analysis is complete.

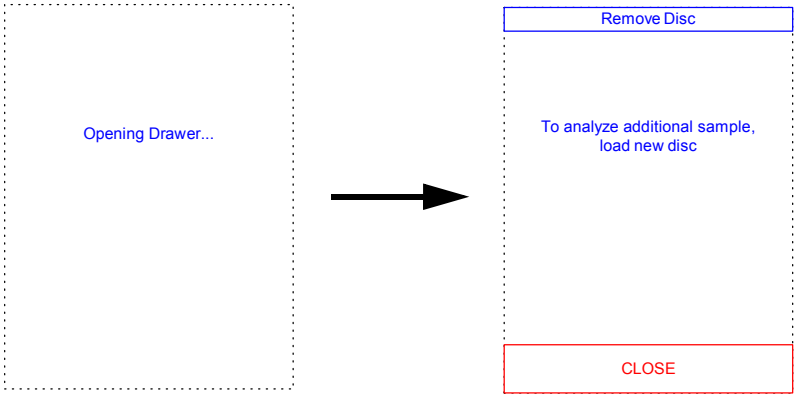


13. By default, the analyzer automatically prints the results of the analysis.

    If the results do not print automatically, they can be recalled from memory and printed — see "Searching for Results" on page 5-3.

    Note: *Be sure to review the results printout for any suppressed results, which are marked with these symbols: ~~~*

14. Press **OPEN** to open the disc drawer.

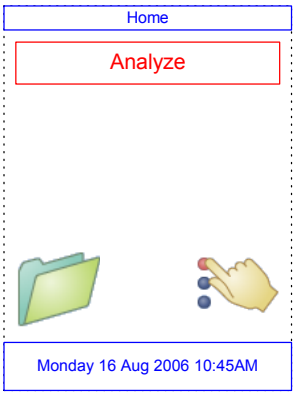


15. Remove the reagent disc from the drawer.

    CAUTION: *Dispose of the disc according to the lab's standard procedures for human patient samples. For additional information, see Section 1.2, "Universal Precautions," on page 1-1.*

16. To analyze another sample, insert the new reagent disc and repeat the above procedure.

17. When finished, press **CLOSE** to close the drawer and return the analyzer to standby mode.

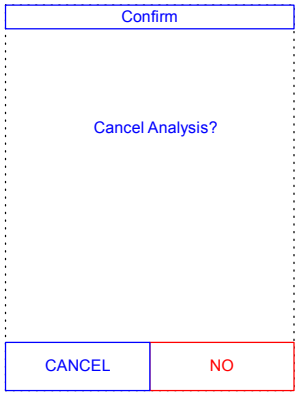


3.4 Canceling Analysis

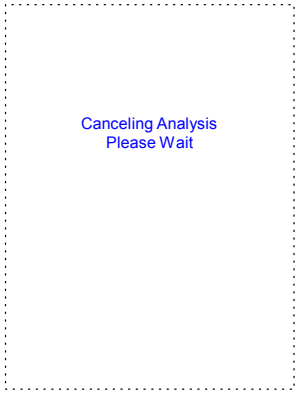
Occasionally you may need to cancel an analysis in progress. Do this as follows.

1. Press **CANCEL** on the touchscreen.

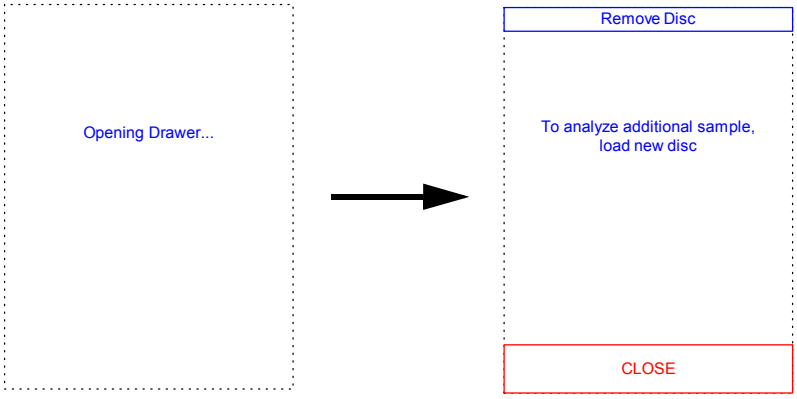
   The display asks for confirmation.



2. Press **CANCEL** again to confirm. The analysis is then canceled.



   The disc drawer then opens.



3. Remove the disc from the drawer. The analyzer is now ready to perform another analysis. Press **CLOSE** to close the drawer.

3.5 Results

The results calculated by the analyzer are stored in memory and printed automatically, and can also be recalled and printed later as needed. If the analyzer is connected to an external computer, the results are automatically transmitted as soon as they are calculated (see Section 10). See Section 8.2, "Principles of Operation" for the basic procedure and equations used to calculate analyte concentrations.

The figure at the right shows the contents of a typical results printout. The heading of the results printout includes information such as the reagent disc type, test date and time, sample type, sample ID number, alternate ID number, gender, age, operator ID number, disc lot number, and analyzer serial number. The test results section of the card is printed in four columns: chemistry name, analyte concentration, reference range, and specified units, as shown at right. The results printout has an adhesive backing so it can easily be placed into the patient's file.

piccolo xpress
Comprehensive Metabolic

25 May 2006			11:11 AM
Sample Type:			Patient
Sample ID:			78
Disc Lot Number:			5200D
Serial Number:			0000P0000C
NA+	137	128-145	mmol/L
K+	4.0	3.6-5.1	mmol/L
tCO2	26	18-33	mmol/L
CL-	103	98-108	mmol/L
GLU	96	73-118	mg/dL
CA	9.2	8.0-10.3	mg/dL
BUN	15	7-22	mg/dL
CRE	0.9	0.6-1.2	mg/dL
ALP	55	42-141	U/L
ALT	29	10-47	U/L
AST	25	11-38	U/L
TBIL	0.9	0.2-1.6	mg/dL
ALB	4.4	3.3-5.5	g/dL
TP	7.3	6.4-8.1	g/dL
QC	OK		
HEM 0	LIP 1+	ICT 1+	

Each reagent disc contains reagents to detect exposure to extreme conditions such as temperature and humidity. The message "QC OK" is printed on the results when results from these reagents are within the expected ranges. Otherwise, no results are printed, and the analyzer opens the disc drawer.

- Results outside the reference range are indicated in the results by an asterisk (*) printed next to the analyte concentration.
- Results outside the dynamic range are indicated in the results by a "less than" symbol (<) printed next to the lowest value of the dynamic range, or a "greater than" symbol (>) printed next to the highest value of the dynamic range.

  For example, the dynamic range of glucose is 10–700 mg/dL. A sample concentration of glucose below this range would be printed as <10 mg/dL, and a concentration above this range would be printed as >700 mg/dL. Results outside the dynamic range should be reported as being below or above the value indicated.
- The symbols "~~~" are printed in place of numbers when a result cannot be determined — that is, when the result is suppressed. A result may be suppressed due to improper mixing of a reagent bead with diluted sample, a nonlinear reaction, an endpoint of a particular reaction not reached, or a concentration outside the analyzer's capabilities. When a chemistry is suppressed (~~~), the analyzer prompts the operator to print an error report.

- **For the lactate dehydrogenase (LD) assay only:**

  Blood cells contain significant levels of LD, and therefore all LD assays are sensitive to hemolysis caused by release of LD from red blood cells. In the following circumstances, the results are annotated to help interpret LD activity in the presence of small amounts of hemolysis.

  - If HEM is greater than 50 and less than or equal to 100 mg/dL, the printed LD value is followed by an "H" indicating additional influence from hemolysis.
  - If HEM is greater than 100 and less than or equal to 150 mg/dL, the LD value is preceded by "<" and followed by "H", indicating that the true LD recovery is less than reported.
  - If HEM is greater than 150, no result will be indicated and only "HEM" will be printed.

- HEM, LIP, or ICT is printed in place of the analyte concentration if hemolysis, lipemia, or icterus, respectively, has adversely affected the results. LIP is also printed if both lipemia and icterus have been affected. HEM is also printed if hemolysis and icterus, hemolysis and lipemia, or hemolysis, lipemia, and icterus have affected a particular analyte. Examine the sample indices to determine if more than one interferent is affecting a particular result.
- The sample indices are included at the bottom of the results printout. These indices indicate the degree of hemolysis, icterus, and lipemia found in the sample. Hemolysis, icterus, and lipemia are measured on a scale of 0 (clear), 1+ (slight), 2+ (moderate), and 3+ (gross).

If the sample is identified as hemolytic, collect a new sample and run another reagent disc. Abaxis recommends that the new sample be separated into serum or plasma so that the degree of hemolysis can be verified. If the new sample is hemolytic, use an alternative testing method or send the sample to a reference laboratory. Samples with hematocrit in excess of 60% packed red cell volume may appear on the result card as HEM. Follow the instructions above for retesting hemolyzed samples.

High lipemia may be due to diet. Ensure the patient has fasted for at least 12 hours before collecting another sample. For suggestions on testing grossly lipemic or icteric samples, see "Troubleshooting" on page 7-1. For grossly lipemic samples from fasting patients or for icteric samples, use an alternative testing method or send the sample to a reference laboratory.

3.6 Testing Procedure Summary

piccolo xpress™ Chemistry Analyzer

- Check that the electrical outlet utilized for the analyzer is grounded.
- Check that the ambient temperature where the analyzer is located is 15–32 ºC (59–90 ºF).
- Do not disconnect the power to the analyzer while running a sample.
- Keep the analyzer drawer closed when not in use.
- Do not attempt to repair the analyzer; this may void the warranty. Refer to Section 7 for troubleshooting and Section 9 for regular maintenance.

Reagent Discs

CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. Do not use a disk that has been dropped.*

*Inspect **every** reagent disc for damage before use. **Never use a damaged disc.***

- Do not use an expired disc. The reagent disc expiration date is printed on the foil pouch and is encoded in the bar code.
- Store all reagent discs at 2–8 ºC (36–46 ºF) as described on their respective pouch labels. Discs may be used directly from the refrigerator.
- Keep reagent discs clean. Use powder-free gloves to handle the discs, and touch the discs only along their edges to eliminate the possibility of fingerprints on the cuvette optical surfaces. If sample spills on the outside of the disc, remove it with a lint-free tissue, and make sure the tissue does not withdraw any sample from the sample port.
- After introducing the sample, hold the reagent disc flat to avoid spillage.
- Never use a reagent disc that has been dropped.
- Use the reagent disc within **20 minutes** of opening the foil pouch.
- Run the reagent disc within **10 minutes** of applying the sample.

Samples

- Analyze whole blood samples within 60 minutes of collection.
- Fill the lithium heparin specimen collection tube at least half-way to ensure the sample does not have a high concentration of anticoagulant.
- To prevent hemolysis, do not refrigerate or shake whole blood samples.
- When adding blood to evacuated collection tubes, remove the needle from the syringe and the stopper from the tube, and gently place the sample into the tube. (If sample is injected through the stopper, hemolysis may occur.)

CAUTION: *Do not remove a sample and then try to reintroduce it into the disc.*

Note: *Always fill evacuated collection tubes in this order: Red, then Green, then Lavender.*

Section 4

Configuring the Analyzer

This section describes how to configure the piccolo xpress™ chemistry analyzer to achieve excellent performance.

Here are the main analysis tasks:

- See "Using the Settings Screens" on page 4-2 for an overview on making settings for the analyzer.
- Change reference ranges to be specific to the patient population, and print, transmit, or archive these ranges.
  - "Customizing Reference Ranges" on page 4-2
  - "Printing and Archiving Reference Ranges" on page 4-12
  - "Transmitting Reference Ranges" on page 4-16
- Change general analyzer settings.
  - "Viewing Analyzer Identification" on page 4-17
  - "Changing Date and Time" on page 4-18
  - "Selecting the Language" on page 4-19
  - "Selecting Units" on page 4-20
  - "Setting Sound Volumes" on page 4-24
  - "Adjusting the Display" on page 4-25
  - "Printer Settings" on page 4-28
  - "Setting Communication Protocol" on page 4-32
  - "Using Optional Data Functions" on page 4-33
- Run control samples — see "Running Controls" on page 4-34.

4.1 Using the Settings Screens

The following shows the general path through the analyzer's menus for performing the procedures in this section. These procedures are available whenever the analyzer displays the Home screen.

1. In the Home screen, press the **Settings** icon.

   The Analyzer Settings screen then appears. From here, adjust the date and time, language, sound, display, and printer, or view basic information about the analyzer.

2. Press the **More Settings** icon.

   This opens the second Analyzer Settings screen. Use this screen as a starting point to make additional settings, work with reference ranges, and update the analyzer's software.

3. Press **Home** to return to the analyzer's Home screen.

4.2 Customizing Reference Ranges

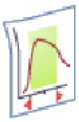
The piccolo xpress™ includes a number of factory-set analyte and demographic reference ranges for use in analysis. You can modify these ranges as needed, as well as create or remove custom ranges, or return all factory ranges to their default settings.

> ***Note:*** *Change reference ranges in either Common units or SI units, not both. The analyzer automatically converts units.*

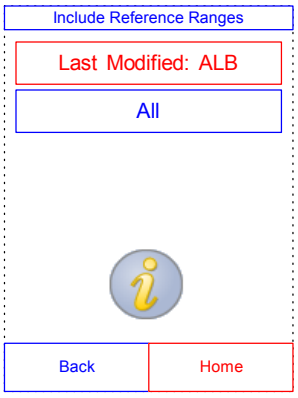
1. In the Home screen, press the **Settings** icon.

2. Press the **More Settings** icon.

3. Press the **Reference Range Settings** icon.



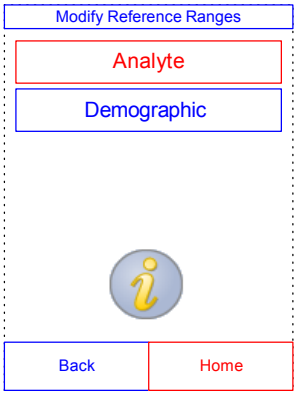
4. Select the reference range to modify:



- To modify the last reference range that was changed, press **Last Modified**, then skip to step 5 on page 4-5.
- To modify any reference range, press **All**, then continue with the next step below.

Note: *Press the information icon for additional help.*

5. The Modify Reference Ranges screen then opens. From here, the following procedures are available:

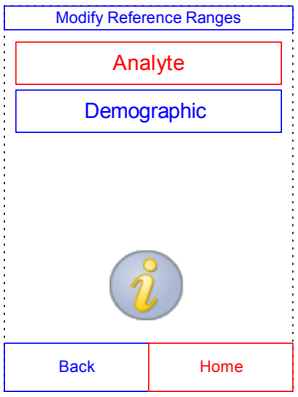


- Modify the reference ranges for a specific analyte — see below.
- Modify the reference ranges for a particular demographic — see page 4-5.
- Add a reference range for a new demographic — see page 4-7.
- Remove a reference range for a demographic — see page 4-10.
- Return all factory reference ranges to their default values — see page 4-11.

Modifying Reference Ranges for an Analyte

Change the reference ranges for a specific analyte as follows.

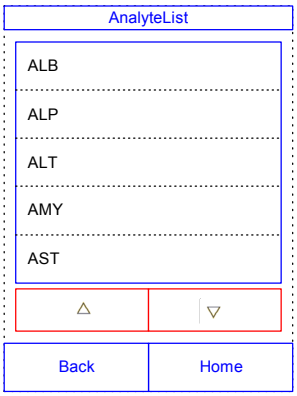
1. In the Modify Reference Ranges screen, press **Analyte**.



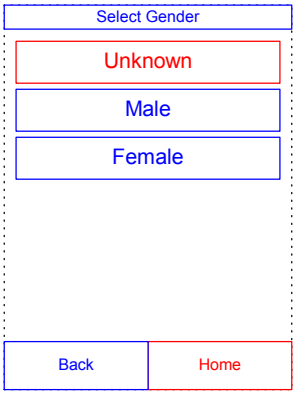
Note: *Press the information icon for additional help.*

2. In the Analyte List screen, select the analyte.

   Use the up (▲) and down (▼) arrow keys as needed to scroll through the list.

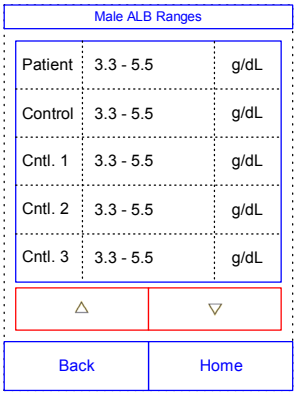


3. Select the patient's gender.

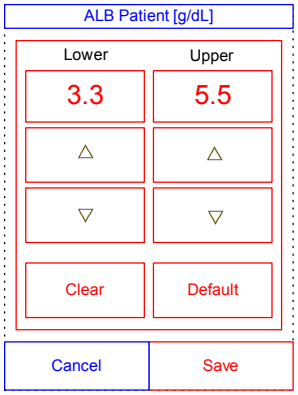


4. Select the reference range to modify.

   Use the up (▲) and down (▼) arrow keys as needed to scroll through the list.



5. Use the controls to set the upper and lower limits for the range.



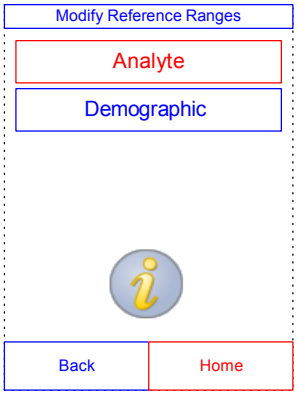
   - ■ Use the up (▲) and down (▼) arrow keys to adjust the values.
   - ■ Press **Clear** to set both limits to zero.
   - ■ Press **Default** to use the factory default values for the range.

6. Press **Save** to store the changes.

Modifying the Reference Ranges for a Demographic

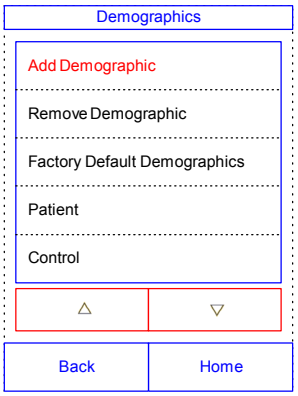
Use this procedure to modify the reference ranges for a particular demographic, patient type, or control.

1. In the Modify Reference Ranges screen, press **Demographic**.



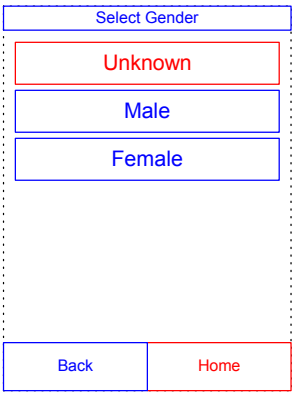
   Note: *Press the information icon* *for additional help.*

2. In the Demographics screen, choose the patient or control demographic to modify.



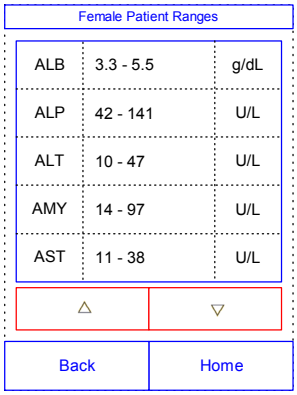
   Use the up (▲) and down (▼) arrow keys as needed to scroll through the list.

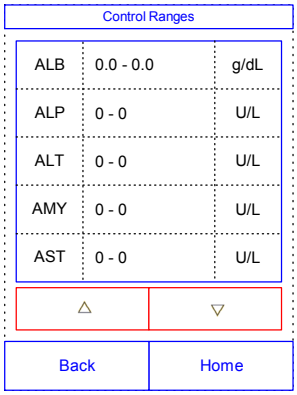
3. **Patient demographic only:** select the gender.



4. The analyzer then displays the ranges for the patient or control demographic.

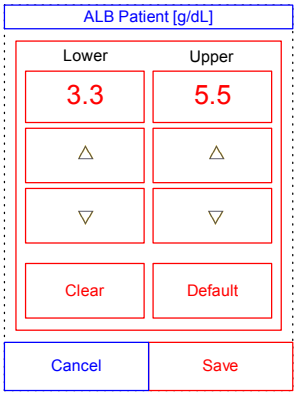
   Select the analyte to adjust. If needed, use the up (▲) and down (▼) arrow keys to scroll through the list.

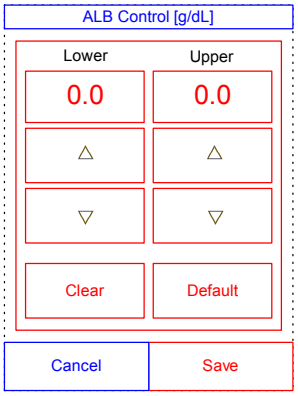




5. Use the controls to set the upper and lower limits for the range.

   - Use the up (▲) and down (▼) arrow keys to adjust the values.
   - Press **Clear** to set both limits to zero.
   - Press **Default** to use the factory default values for the range.



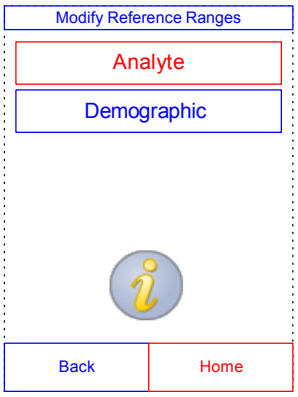


6. Press **Save** to store the changes.

Adding a Demographic

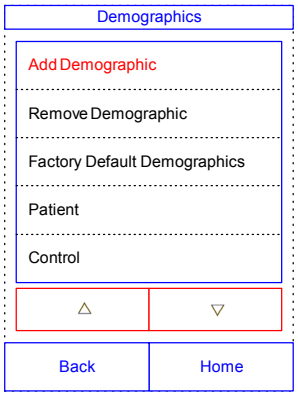
Use this procedure to add reference ranges for a particular demographic.

1. In the Modify Reference Ranges screen, press **Demographic**.



Note: *Press the information icon for additional help.*

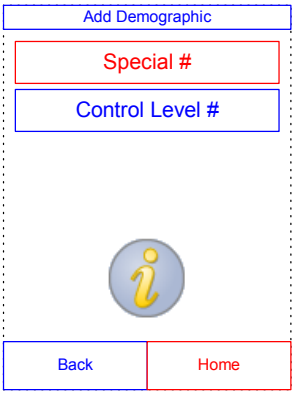
2. In the Demographics screen, press **Add Demographic**.



■ To create a reference range for a new, unnamed demographic:

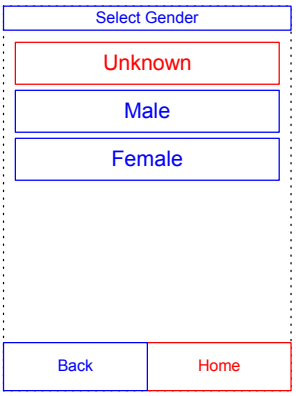
a. Press **Special #**.

(Press the information icon for additional help.)

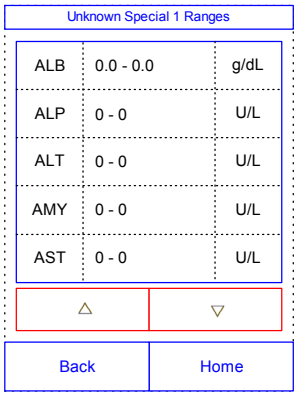


Note: *The displayed number # depends on the number of special or control level demographics that have already been added or deleted.*

b. Select the gender.

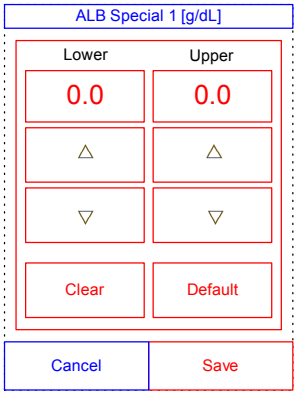


c. Set minimum and maximum values for each of the analytes to be included in the range:



i. Select the analyte to adjust. If needed, use the up (▲) and down (▼) arrow keys to scroll through the list.

ii. Use the control values to set upper and lower limits for the analyte.



- ❑ Use the up (▲) and down (▼) arrow keys to adjust the values.

Note: *Entering zero for both values suppresses printing of the ranges for this analyte in results (blanks appear instead), and also suppresses checking the recovered value against the range limits.*

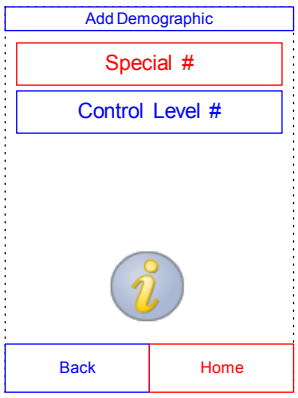
- ❑ Press **Clear** to set both limits to zero.
- ❑ Press **Default** to use the factory default values for the range.

d. Press **Save** to store the changes.

■ To create a new control:

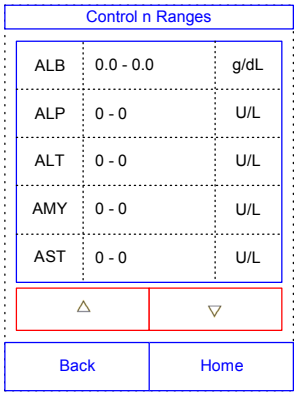
a. Press **Control Level #**.

(Press the information icon for additional help.)



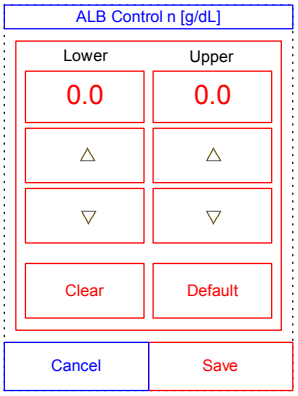
b. Set minimum and maximum values for each of the analytes to be included in the range:

i. Select the analyte to adjust from the list. If needed, use the up (▲) and down (▼) arrow keys to view the entire list.



ii. Use the controls to set upper and lower limits for the analyte.

❑ Use the up (▲) and down (▼) arrow keys to adjust the values.



Note: *Entering zero for both values suppresses printing of the ranges for this analyte in results (blanks appear instead), and also suppresses checking the recovered value against the range limits.*

❑ Press **Clear** to set both limits to zero.

❑ Press **Default** to use the factory default values for the range.

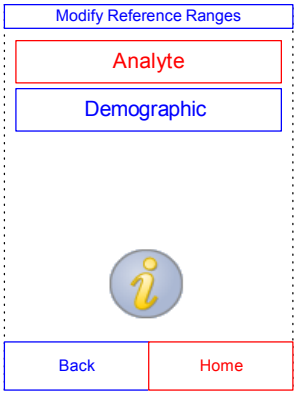
c. Press **Save** to store the changes.

Removing a Demographic

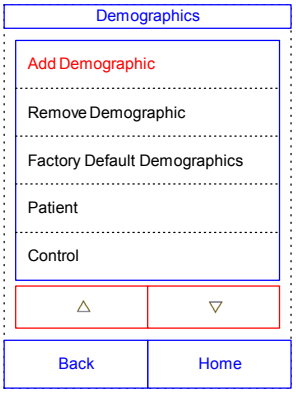
Use this procedure to remove the reference ranges for a particular demographic.

1. In the Modify Reference Range screen, press **Demographic**.

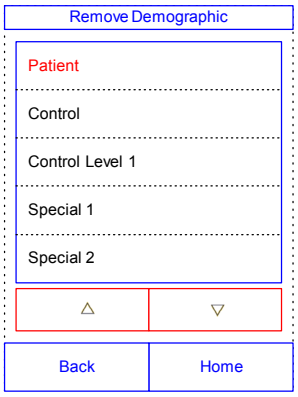
   Note: *Press the information icon* *for additional help.*



2. In the Demographics screen, press **Remove Demographic**.

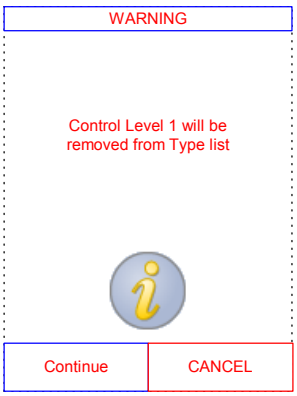


3. Select the demographic to remove. Use the up (▲) and down (▼) arrow keys to scroll through the list.



4. A warning screen then appears. Press **Continue** to permanently remove the demographic.

   (Press the information icon for additional help.)

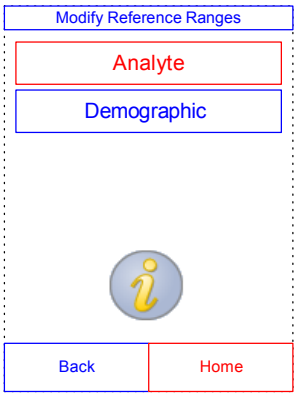


Restoring Factory Default Demographics

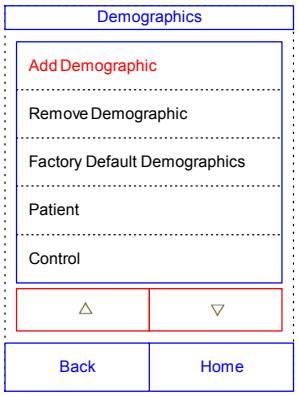
Use this procedure to restore all factory reference ranges to their default settings.

1. In the Modify Reference Ranges screen, press **Demographic**.

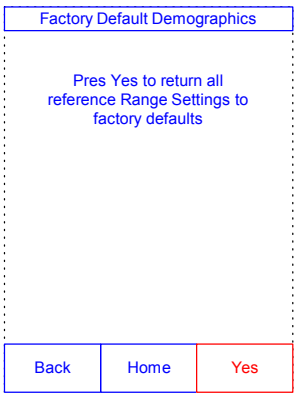
   Note: *Press the information icon for additional help.*



2. In the Demographics screen, press **Factory Default Demographics**.



3. Press **Yes**.



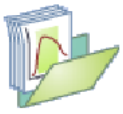
4.3 Printing and Archiving Reference Ranges

Reference ranges can be printed, or stored in the analyzer as archive files for later use or review.

1. In the Home screen, press the **Settings** icon.

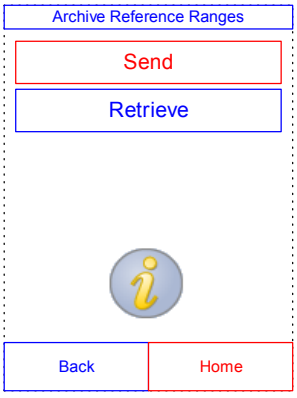
2. Press the **More Settings** icon.

3. Press the **Archive Reference Ranges** icon.



4. Press **Send**.

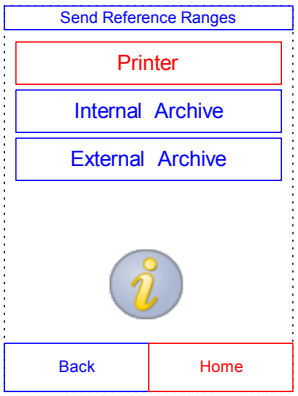
Note: *Press the information icon* *for additional help.*



■ To archive the reference ranges into the analyzer's internal memory: press **Internal Archive**.

The reference range is then stored in the analyzer under the current date and time.

(Press the information icon for additional help.)



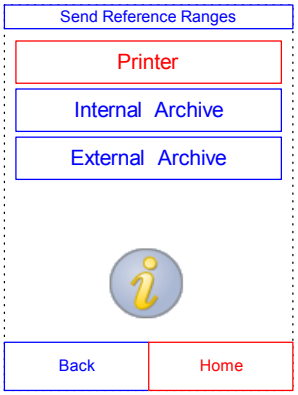
Note: *See "Retrieving Reference Ranges" for instructions on retrieving stored archives.*

■ To archive the ranges onto a PC connected to the analyzer, see page 4-16. (See page 10-1 for instructions on connecting a PC to the analyzer.)

■ To print a range or ranges:

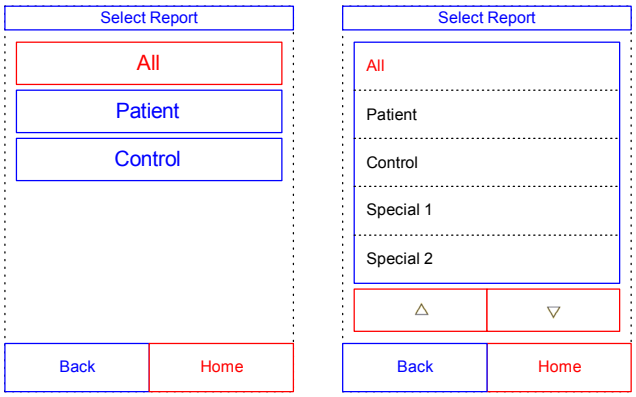
a. Press **Printer**.

(Press the information icon for additional help.)



b. Select the report type to print (the left diagram shows the default choices, the right shows typical customized choices).

All prints controls and patients.



c. The reference range (or ranges) is then printed.

4.4 Retrieving Reference Ranges

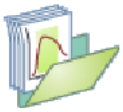
Reference ranges can be retrieved from archives as follows.

> ***Note:*** *Retrieving an archived reference range overwrites all reference range values currently in the analyzer. Consider archiving the current reference ranges before retrieving another set.*

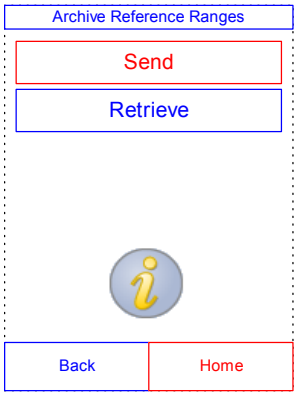
1. In the Home screen, press the **Settings** icon.

2. Press the **More Settings** icon.

3. Press the **Archive Reference Ranges** icon.

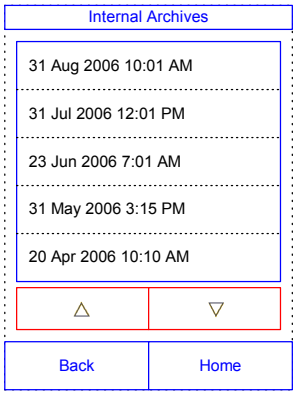


4. Press **Retrieve**.

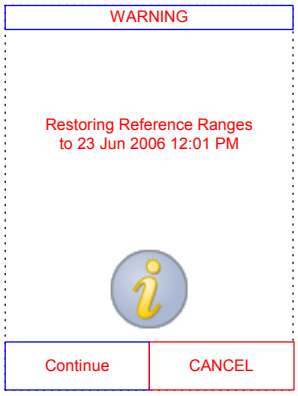


Note: *Press the information icon for additional help.*

5. Select the archive to retrieve. Use the up (▲) and down (▼) arrow keys as needed to scroll through the list.



6. A warning screen then appears. Press **Continue** to retrieve the archived reference range.



(Press the information icon for additional help.)

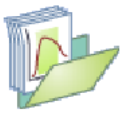
4.5 Transmitting Reference Ranges

Reference ranges can be transmitted to a connected PC and stored for later use or review.

1. In the Home screen, press the **Settings** icon.

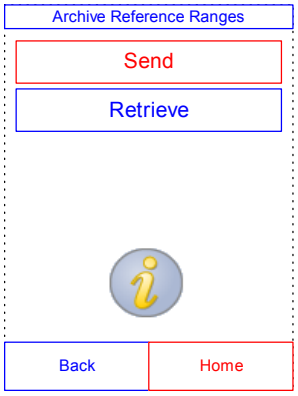
2. Press the **More Settings** icon.

3. Press the **Archive Reference Ranges** icon.



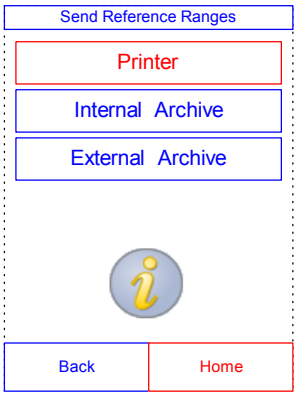
4. Press **Send**.

   Note: *Press the information icon* *for additional help.*

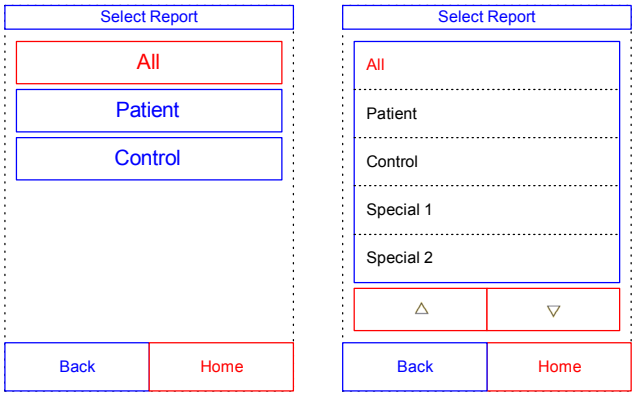


5. Press **External Archive**.

   (Press the information icon for additional help.)



6. Select the report type (the type of ranges) to send to the PC.



The reference range is then sent to the PC and stored under the current date and time.

Note: *See "Retrieving Reference Ranges" for instructions on retrieving stored archives.*

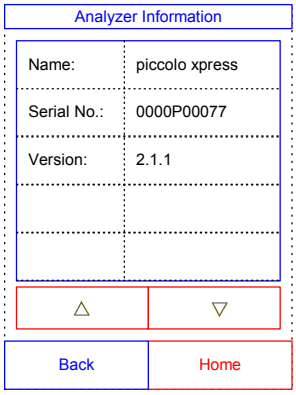
4.6 Viewing Analyzer Identification

Use this function to verify information about the analyzer, such as its serial number, the version of the installed software, and information about the tests that have been run and printed.

1. In the Home screen, press the **Settings** icon.

2. Press the **Analyzer Information** icon.

3. The display then shows the analyzer information.



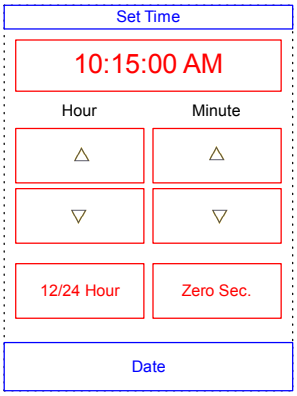
4.7 Changing Date and Time

The date and time is factory preset to Pacific Time. Verify the date and time when the analyzer is removed from its shipping carton.

1. In the Home screen, press the **Settings** icon.

2. Press the **Date and Time** icon.

3. In the Set Time screen, use the controls to set the time:
   - Use the up (▲) and down (▼) arrow keys to adjust the hour and minutes.
   - Press **12/24 Hour** to switch between 12- and 24-hour time formats.
   - Press **Zero Sec.** to set the seconds to zero.

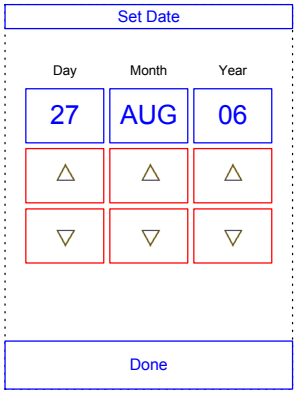


4. Press **Date** when the time is set.

Note: *If the time entered is invalid, an error message appears — press* ***Continue****, set the correct time, then press* ***Done****.*

5. In the Set Date screen, use the up and down arrow keys to adjust the day, month, and year.

6. Press **Done** when the date is set.



Note: *If the date entered is invalid, an error message appears — press* ***Continue*** *and set the correct date.*

4.8 Selecting the Language

The analyzer provides several languages for menus, the keyboard, and printing. Select the language to use (English USA is the default) as follows.

1. In the Home screen, press the **Settings** icon.

2. Press the **Languages** icon.

3. Select the display language from the list. If needed, use the up (▲) and down (▼) arrow keys to view the entire list.

4. Select the keyboard type from the list. Use the up (▲) and down (▼) arrow keys to scroll through the list.

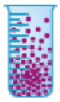
4.9 Selecting Units

Use this procedure to set the units used by the analyzer and in results: Common units (mg/dL, etc.) or SI units (Systeme International) (mmol/L, etc.).

1. In the Home screen, press the **Settings** icon.

2. Press the **More Settings** icon.

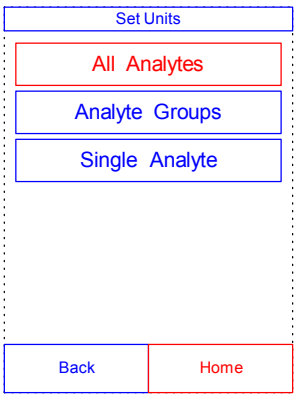
3. Press the **Units Settings** icon.



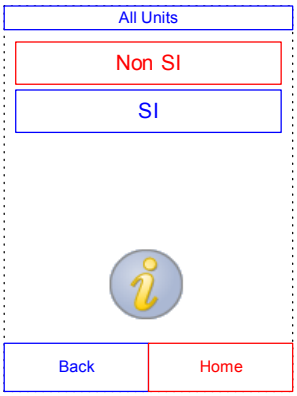
4. Set the units used for all analytes, a particular analyte, or a group of analytes as follows.

   ■ To set units for all analytes:

   a. Press **All Analytes**.



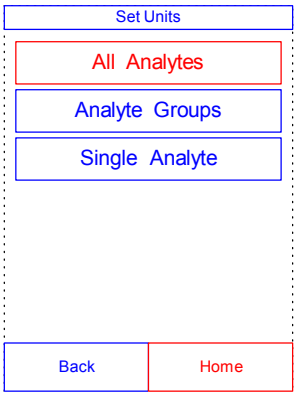
b. Select the units to use for all analytes: **Non SI** or **SI**.



Note: *Press the information icon* *for additional help.*

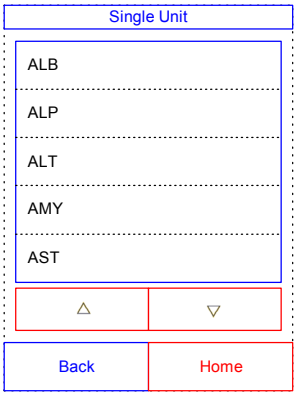
■ To set the units for a particular analyte:

a. Press **Single Analyte**.

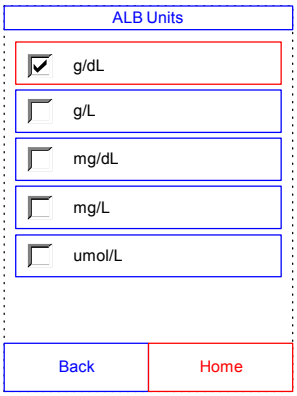


b. Select the analyte from the list.

Use the up (▲) and down (▼) arrow keys as needed to scroll through the list.

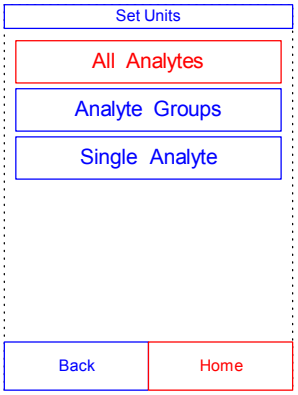


c. Select the units to use for the analyte: **g/dL**, **g/L**, **mg/dL**, **mg/L**, or **umol/L**.

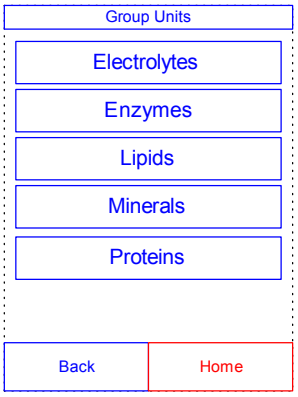


■ To set units for a group of analytes (electrolytes, enzymes, lipids, minerals, or proteins):

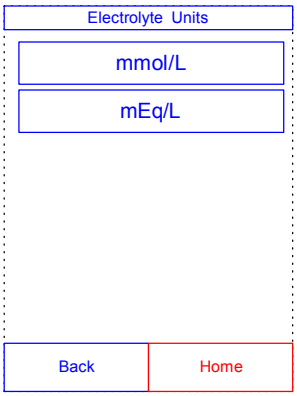
a. Press **Analyte Groups**.



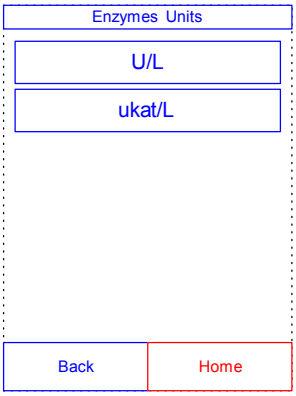
b. Press to select the analyte group: **Electrolytes**, **Enzymes**, **Lipids**, **Minerals**, or **Proteins**.



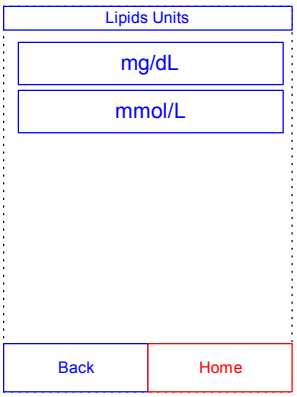
- For electrolytes: select **mmol/L** or **mEq/L**.



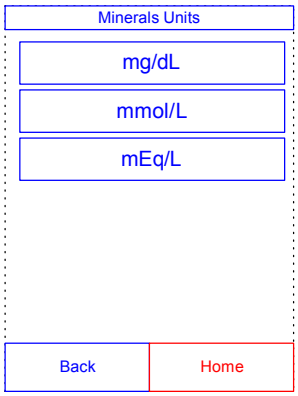
- For enzymes: select **U/L** or **ukat/L**.



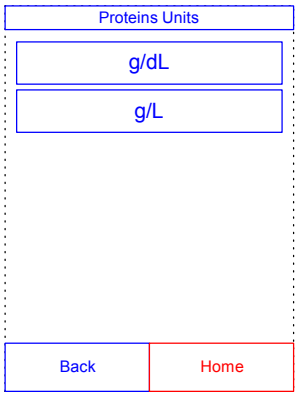
- For lipids: select **mg/dL** or **mmol/L**.



- For minerals: select **mg/dL**, **mmol/L**, or **mEq/L**.



- For proteins: select **g/dL** or **g/L**.



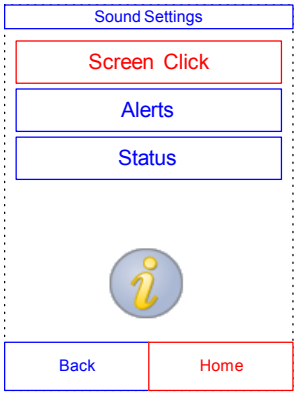
4.10 Setting Sound Volumes

Use this procedure to adjust the volume of the sounds used for the analyzer's screen click, alert, and status notification.

1. In the Home screen, press the **Settings** icon.

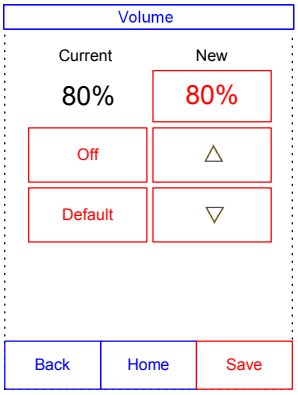
2. Press the **Sound Settings** icon.

3. Select the sound to adjust.



Note: *Press the information icon* *for additional help.*

4. Use the controls to set the selected volume.



- Use the up (▲) and down (▼) arrow keys to adjust the volume.
- Press **Off** to turn the sound off.
- Press **Default** to set the sound to its factory default value.

5. Press **Save** to store the new setting.

4.11 Adjusting the Display

The brightness of the analyzer's display can be adjusted as needed, and the display's touchscreen can be calibrated for best performance. In addition, the time the analyzer must be inactive before it activates a screen saver or enters power-saving mode can be set as required. (For either, touch the screen to wake the analyzer.)

1. In the Home screen, press the **Settings** icon.

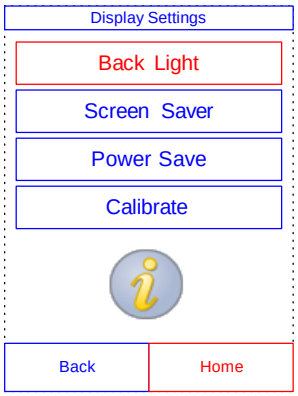
2. Press the **Display Settings** icon.

3. Adjust or calibrate the display as follows.

■ To adjust the backlight brightness:

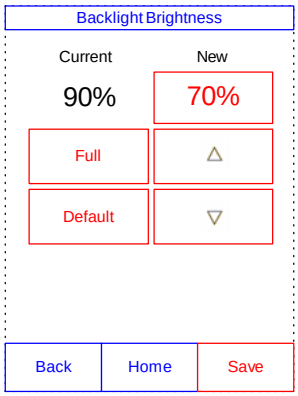
a. Press **Back Light**.

(Press the information icon for additional help.)



b. Use the controls to set the brightness:

- ❑ Use the up (▲) and down (▼) arrow keys to adjust the brightness level.
- ❑ Press **Full** to select maximum brightness.
- ❑ Press **Default** to set the brightness to its factory default.

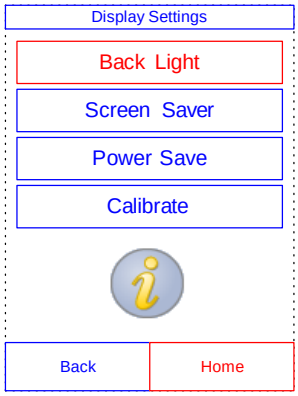


c. Press **Save** to store the new setting.

■ To adjust the screen saver delay:

a. Press **Screen Saver**.

(Press the information icon for additional help.)



b. Use the controls to set the delay.

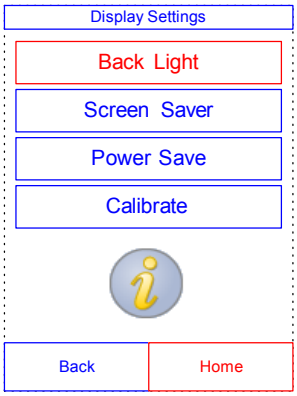
- ❑ Use the up (▲) and down (▼) arrow keys to adjust the delay.
- ❑ Press **Never** to turn off the screen saver.
- ❑ Press **Default** to set the delay to its factory default.

c. Press **Save** to store the new setting.

■ To adjust power-saving delay:

a. Press **Power Save**.

(Press the information icon for additional help.)



b. Use the controls to set the delay.

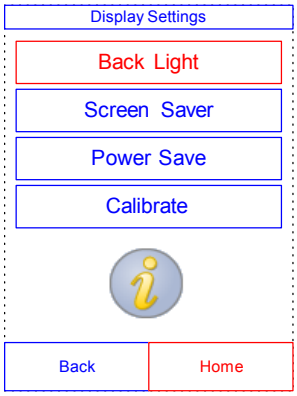
- ❑ Use the up (▲) and down (▼) arrow keys to adjust the delay.
- ❑ Press **Never** to prevent the analyzer from entering power-saving mode.
- ❑ Press **Default** to set the delay to its factory default.

c. Press **Save** to store the new setting.

■ To calibrate the display's touchscreen:

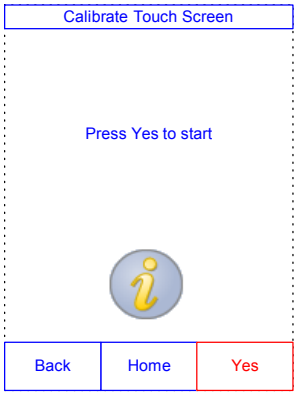
a. Press **Calibrate**.

(Press the information icon for additional help.)



b. Press **Yes** to start the calibration process, and follow the on-screen instructions.

(Press the information icon for additional help.)



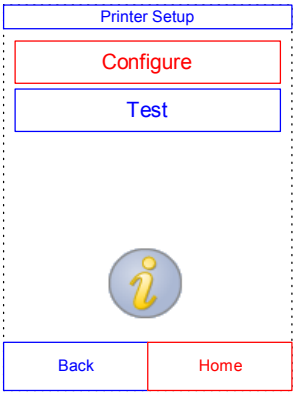
4.12 Printer Settings

Use the procedures in these pages to set up and configure the analyzer's internal printer, or an external printer connected to the analyzer.

1. In the Home screen, press the **Settings** icon.

2. Press the **Printer Settings** icon.

3. The Printer Setup screen is then displayed.



- To select the default printer to be used with the analyzer, see "Setting the Default Printer" below.
- To test a printer for proper function, see "Testing a Printer" on page 4-30.
- To select which reports can be printed automatically after an analysis, see "Selecting Reports" on page 4-31.

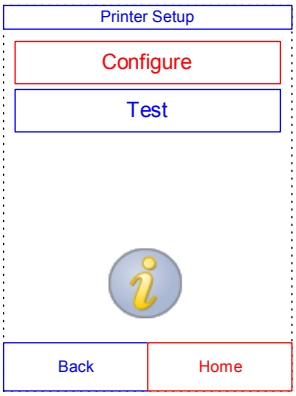
Note: *Press the information icon for additional help.*

Setting the Default Printer

This procedure selects the printer that the analyzer will use for printing results and reports.

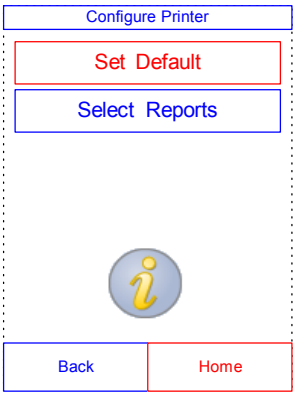
1. In the Printer Setup screen, press **Configure**.

Note: *Press the information icon for additional help.*

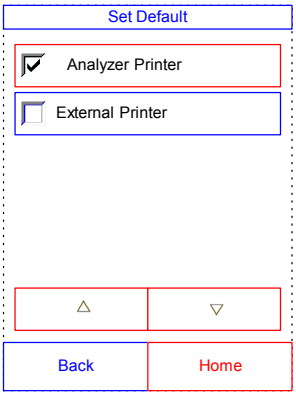


2. Press **Set Default**.

(Press the information icon for additional help.)



3. Select the **Analyzer Printer** or an **External Printer**.



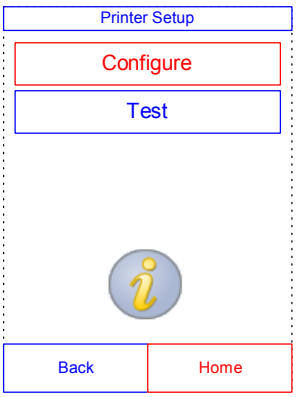
4. **External Printer only:** select the printer from the displayed list of available printers. The analyzer then detects automatically detects the type of printer and configures it as needed.

Testing a Printer

Test the function of the analyzer's printer or a connected external printer as follows.

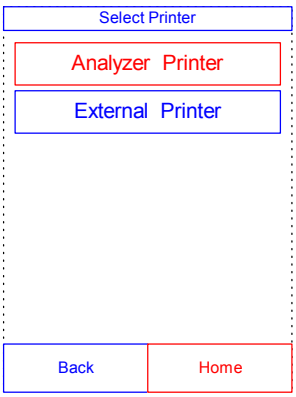
1. In the Printer Setup screen, press **Test**.

   Note: *(Press the information icon* *for additional help.)*



2. Select the printer to test.

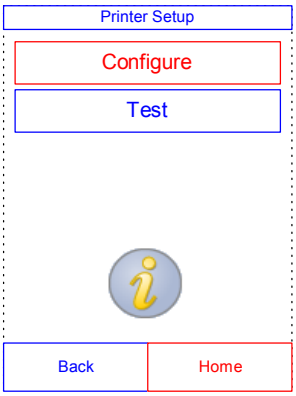
   The selected printer then outputs a test page.



Selecting Reports

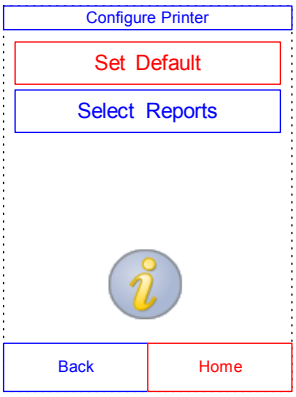
Use this procedure to set the type and number of reports that can be printed automatically after a sample is analyzed.

1. In the Printer Setup screen, press **Configure**.



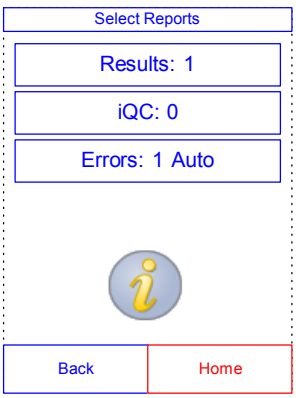
Note: *Press the information icon for additional help.*

2. Press **Select Reports**.



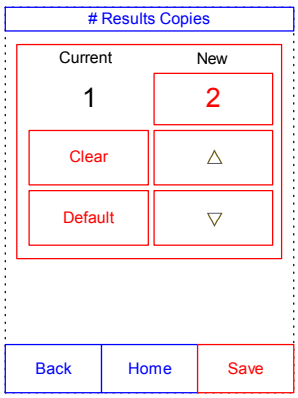
(Press the information icon for additional help.)

3. Select the report type.



(Press the information icon for additional help.)

4. Use the controls to adjust the number of copies to print:



   - ■ Use the up (▲) and down (▼) arrow keys to adjust the number.
   - ■ Press **Clear** to set the number to zero.
   - ■ Press **Default** to use the factory default value.

5. Press **Save** to store the new setting.

4.13 Setting Communication Protocol

To transmit results and other information from the analyzer to an external computer, specify the communication protocol to be used.

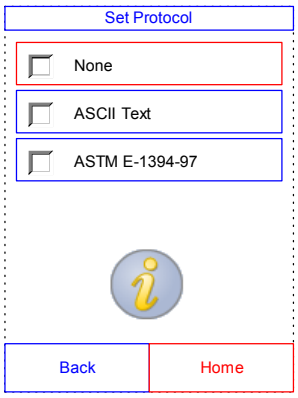
1. In the Home screen, press the **Settings** icon.

2. Press the **More Settings** icon.

3. Press the **Communication Settings** icon.

4. Select a protocol: **ASCII Text**, **ASTM E-1394-97**, or **None**.

   Note: *Press the information icon* *for additional help.)*



4.14 Using Optional Data Functions

The piccolo xpress™ includes a number of optional data-entry functions that can be used to enter more detailed information about samples, such as age and gender. The analyzer can be configured to use some or all of these functions as needed.

Note: *The analyzer includes a number of optional data functions that can be used to enter more detailed information about samples.*

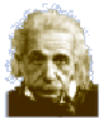
In this manual, the steps for these optional functions are marked with the Advanced Setting icon:

The screens for these optional functions appear on the analyzer only if the functions are enabled. ***If a screen shown in a procedure step in this manual does not appear on the analyzer screen, skip that step.*** *(See* "Using Optional Data Functions" on page 4-33 *for details about these functions.)*

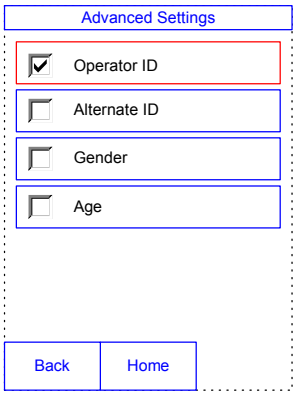
1. In the Home screen, press the **Settings** icon.

2. Press the **More Settings** icon.

3. Press the **Advanced Settings** icon.

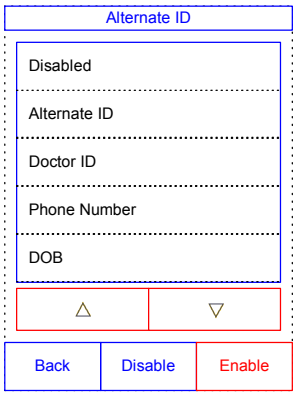


4. In the Advanced Settings screen, select the types of information that will need to be entered during the analysis process.



5. **Alternate ID only:** select an alternate ID item to be entered (such as Doctor ID, Phone #, DOB, Admission ID, and Patient ID).

   Use the up (▲) and down (▼) arrow keys to scroll through the list.



4.15 Running Controls

A control is a biological sample or solution with a suitably contrived matrix that is analyzed for purposes of quality control. The composition of the matrix must be such that the solution closely matches that of the biological specimen for characteristics of importance to the analyzer. Control materials need to be stable and available in sufficient volumes in multiple portions and over an extended period. Many control products are available commercially. Assayed controls also come with expected values of the analytes for guidance.

Abaxis recommends control testing as follows:

- at least every 30 days
- whenever laboratory conditions have changed significantly
- when training or retraining of personnel is indicated
- when test results do not match patient symptoms or clinical findings

Good laboratory practices include the recording of the QC data according to the laboratory's established written procedures. A permanent record of control results should be retained.

Samples and controls are run identically by the analyzer. However, using the Run Controls option in the Menu function stores control results separately from patient results in the analyzer memory. Control results can be printed on a result card immediately after the conclusion of the control run, or whenever the control run results are recalled. (See Section 5 for information on using the RECALL key.) Control results are automatically transmitted to a linked computer.

Handle the control as described in the control package insert. Call Abaxis Technical support for assistance in interpreting control results.

The analyzer automatically stores control results in a memory separate from the patient results memory. The Recall function can be used to search for specific control results without searching through all patient results stored in memory.

Note: *Before a control can be run, a control level must be enabled in the reference ranges — see* page 4-9.

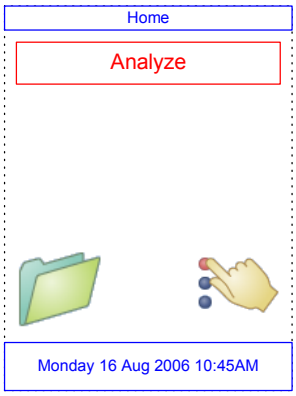
Controls can be run whenever the analyzer displays the Home screen.

Note: *For more details on running controls, see* "Preparing the Reagent Disc" on page 3-2.

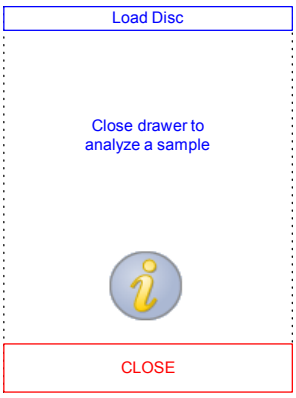
CAUTION: *Discs are fragile — always handle with care. Do not tap discs on the table or work bench to empty the sample port. Do not use a disk that has been dropped.*

*Inspect **every** reagent disc for damage before use. **Never use a damaged disc.***

1. In the Home screen, press **Analyze** to open the disc drawer.



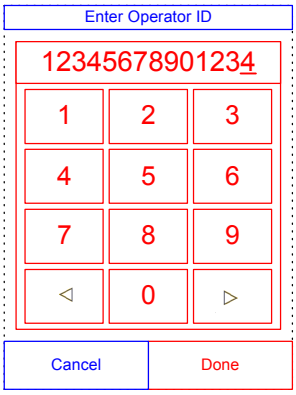
2. Place the disc in the drawer, then press **CLOSE** to close the drawer and start analysis.



Analysis then begins.

Note: *Press the information icon for additional help.*

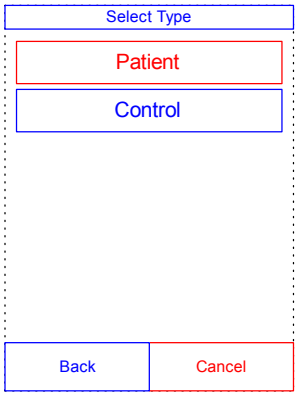
3. **Optional:** Enter the Operator ID, then press **Done**.

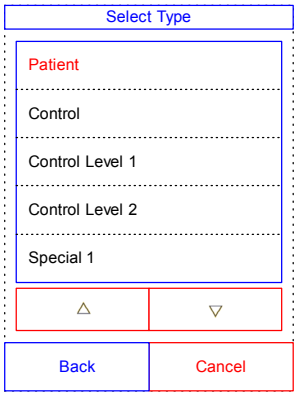


The right arrow key (▶) functions as a dash (–), and the left arrow key (◀) functions as a backspace.

Note: *The Operator ID is a number of up to 14 digits.*

4. Select the control type to use.





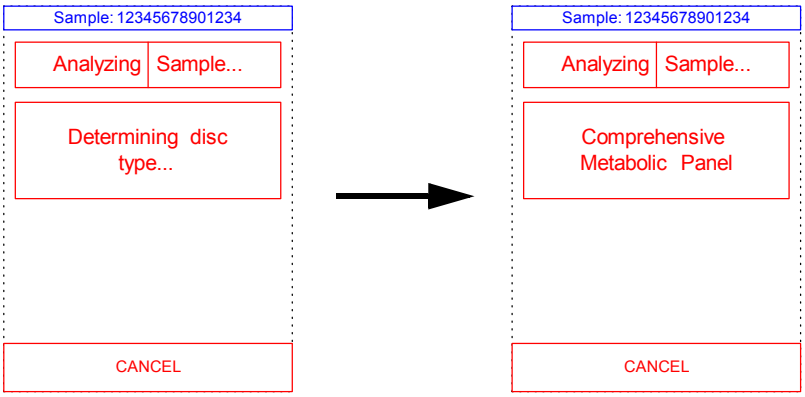
Use the up (▲) and down (▼) arrow keys as needed to scroll through the list.

The screen shown on the left is the default: **Control** is the default choice. (The screen at right shows custom entries.)

5. Enter an ID number for the sample (up to 14 characters), then press **Done**.

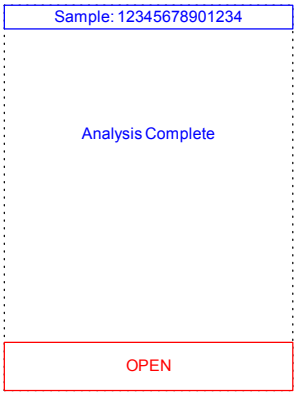
   The right arrow key (▶) functions as a dash (–), and the left arrow key (◀) functions as a backspace.

6. The analyzer then checks the disc type, and then begins processing the sample with no further input.



7. When the sample is finished processing, the analyzer shows that the analysis is complete, and automatically prints the results of the analysis.

   If the results do not print automatically, they can be recalled from memory and printed — see Section 5.2, “Searching for Results” on page 5-3.



8. Press **OPEN** to open the disc drawer, and remove the reagent disc from the drawer.

   CAUTION: *Dispose of the used reagent disc according to the lab’s biohazard procedures.*

9. When finished, press **CLOSE** to close the drawer.

Section 5

Recalling Results

The piccolo xpress™ chemistry analyzer includes a Recall function that provides access to the results of the most recent tests, including patient results, control results, and test errors.

The Recall function is available from the analyzer's Home screen.

The operator can search results by sample ID number or date, or view patient results or control results by date. The operator can also view the results in memory one record at a time. The results can then be printed, or transmitted to a computer.

Troubleshooting Flags

The piccolo xpress™ performs a series of internal quality checks to ensure accurate results. When the analyzer detects a problem, it either suppresses certain chemistry results (in which case it prints trouble-shooting "flags" — ~~~, HEM, LIP, or ICT — in place of values), or cancels the run (the disc cancels and no results are printed). When either of these situations occur, print or transmit an error report as described in Section 5.2.

The remainder of this section includes instructions for recalling, viewing, and printing or transmitting results and reports:

- Section 5.1, "Recalling the Results of the Last Disc Run," on page 5-2
- Section 5.2, "Searching for Results," on page 5-3
- Section 5.3, "Browsing Results," on page 5-8
- Section 5.4, "Transmitting All Results," on page 5-10

Note: *The analyzer must be connected to a computer to transmit results — see Section 10 for instructions.*

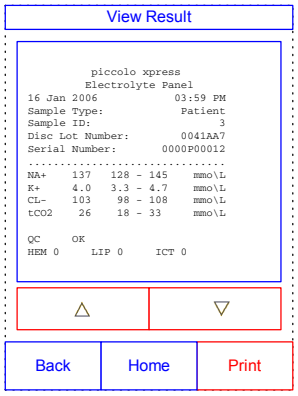
5.1 Recalling the Results of the Last Disc Run

Use this procedure to recall, print, and transmit the results of the last disc run.

1. In the Home screen, press the **Recall** icon:

2. Press **Last Disc**.

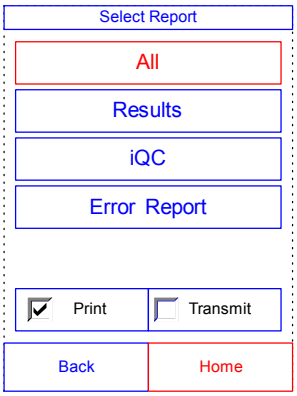
3. The results from the last disc are now available for review. Use the up (▲) and down (▼) arrow keys to scroll through the results.



4. To print these results or transmit them to an external computer, press **Print**:

   a. Select **Print** and/or **Transmit**.

   b. Select the report: **All**, **Results**, **iQC**, or **Error Report**.



   Note: *If the disc produced no results, only the Error Report option will be available.*

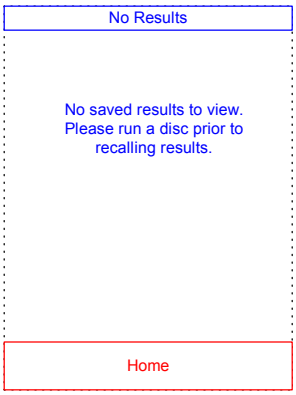
   The display shows "Sending Report..." while the report or results are being printed or transmitted.

5.2 Searching for Results

Use the Recall function to search for a particular record according to its sample ID number or date, or to view a list of all saved patient or control results sorted by date.

1. In the Home screen, press the **Recall** icon.

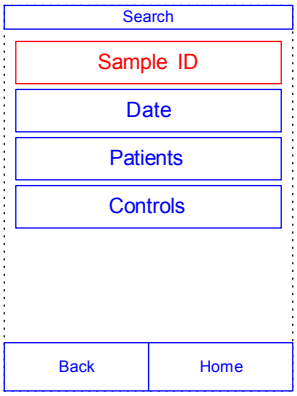
Note: *If the analyzer contains no saved results, it displays the message shown at right.*



2. Press **Search**.

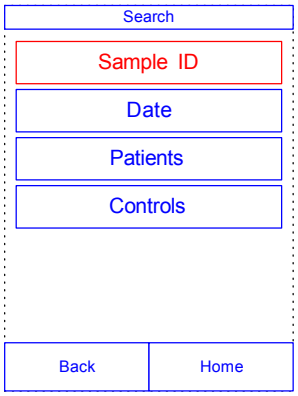
Use the Search screen to search for results:

- To search for results by sample ID, see page 5-4.
- To search for results by date, see page 5-6.
- To view patient results or control results sorted by date, see page 5-7.



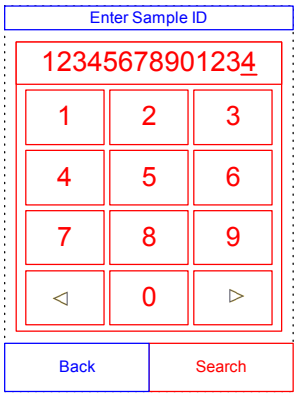
Searching for Results by Sample ID

1. In the Search screen, press **Sample ID**.



2. Enter the sample ID number.

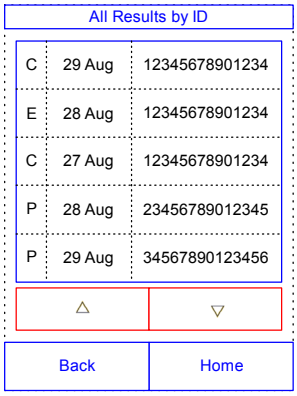
   Use the right arrow key (▶) to enter dashes (–), and the left arrow key (◀) to backspace.



3. Press **Search**.

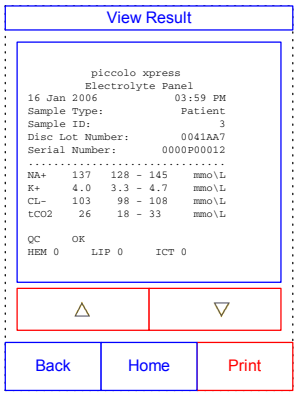
The analyzer then displays a list of results (**P**atient, **C**ontrol, and **E**rror) sorted first by sample ID, then by date. Any samples with the ID number entered will be at the top, followed by the next-closest matches.

Use the up (▲) and down (▼) arrow keys to scroll through the list. (The list wraps around when either end is reached.)



4. Press to select and display the particular results.

   Use the up (▲) and down (▼) arrow keys to scroll through the results.

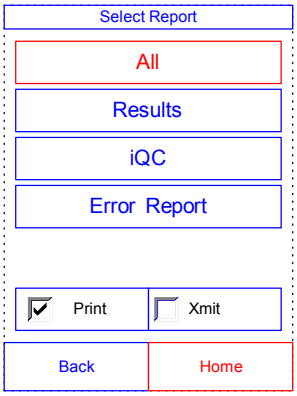


5. To print these results or transmit them to an external computer, press **Print**.

   a. Select **Print** or **Xmit** (transmit).

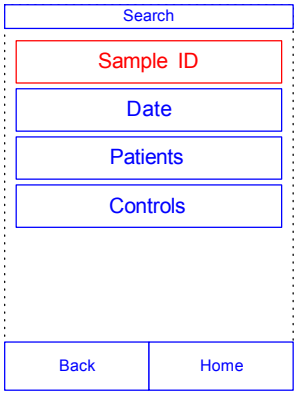
   b. Select the report to print or transmit: **All**, **Results**, **iQC**, or **Error Report**.

      The display shows “Sending Report...” while the report is being printed or transmitted.



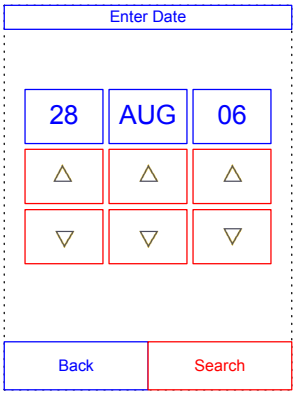
Searching for Results by Date

1. In the Search screen, press **Date**.



2. Enter the date of the results you want to search for.

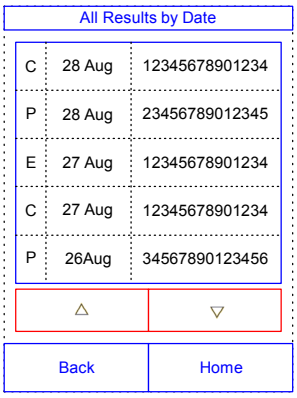
   Use the up (▲) and down (▼) arrow keys to adjust the day, month, and year.



3. Press **Search**.

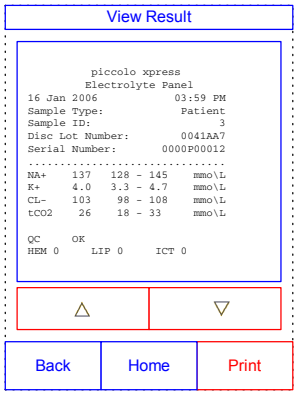
   The analyzer then displays a list of results in reverse chronological order, beginning with the date entered.

   Use the up (▲) and down (▼) arrow keys to scroll through the list.



4. Press to display the results.

   Use the up (▲) and down (▼) arrow keys to scroll through the results.

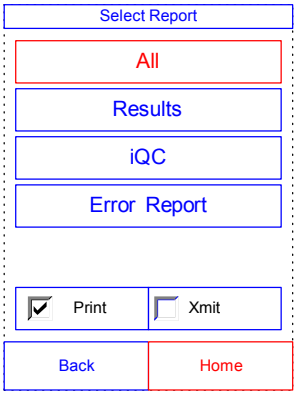


5. To print these results or transmit them to an external computer, press **Print**.

   a. Select **Print** or **Xmit** (transmit).

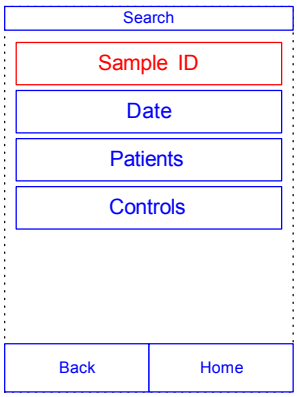
   b. Select the report to print or transmit: **Results**, **iQC**, **Error Report**, or **All**.

      The display shows "Sending Report..." while the report is being printed or transmitted.



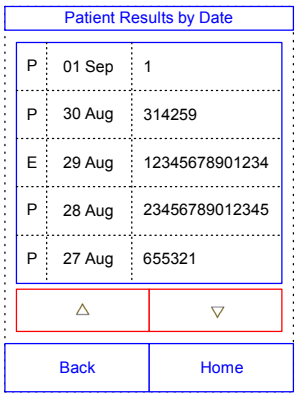
Viewing Patient Results or Control Results by Date

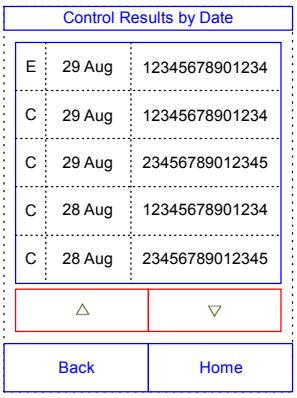
1. In the Search screen, press **Patients** or **Control**.



The analyzer then displays a list of patient results (**P**) and errors (**E**) (shown at right) or control results (**C**) and errors (**E**) (at far right) in reverse chronological order, beginning with the date entered.

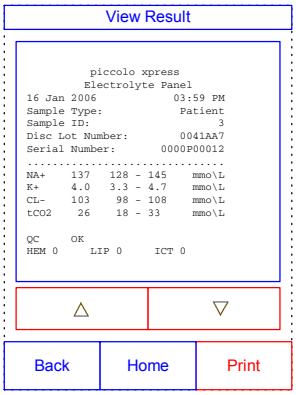
Use the up (▲) and down (▼) arrow keys to scroll through the list.





2. Select the results to display.

   Use the up (▲) and down (▼) arrow keys to scroll through the results.

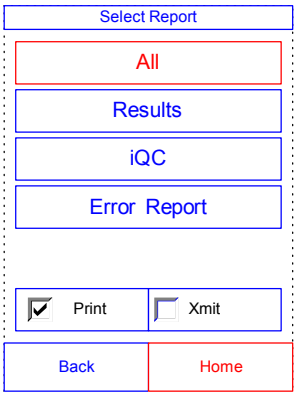


3. To print these results or transmit them to an external computer, press **Print**.

   a. Select **Print** or **Xmit** (transmit).

   b. Select the report to print or transmit: **Results**, **iQC**, **Error Report**, or **All**.

      The display shows “Sending Report...” while the report is being printed or transmitted.



5.3 Browsing Results

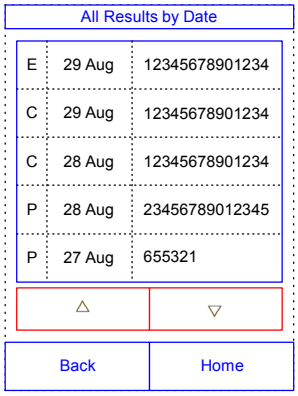
Use the Recall function to browse through all stored results.

1. In the Home screen, press the **Recall** icon:

2. Press **Browse**.

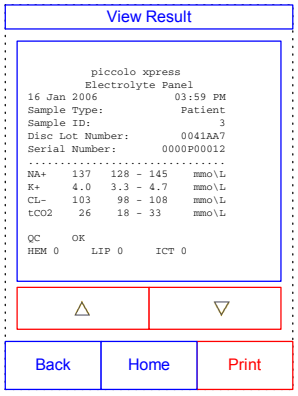
The analyzer then displays a list of all results (**P**atient, **C**ontrol, and **E**rror) in reverse chronological order, beginning with the date entered.

Use the up (▲) and down (▼) arrow keys to scroll through the list and find the needed results.



3. Press to display the results.

Use the up (▲) and down (▼) arrow keys to scroll through the results.

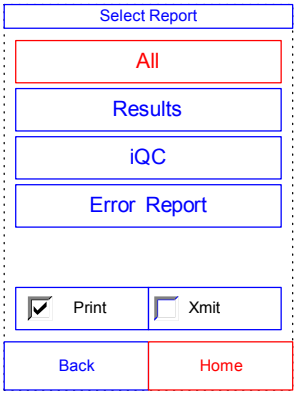


4. To print these results or transmit them to an external computer, press **Print**.

   a. Select **Print** or **Xmit** (transmit).

   b. Select the report to print or transmit: **All**, **Results**, **iQC**, or **Error Report**.

      The display shows “Sending Report...” while the report is being printed or transmitted.



5.4 Transmitting All Results

Use this procedure to transmit all stored results to a connected computer.

Note: *See Section 10 for connection instructions.*

1. In the Home screen, press the **Recall** icon:

2. Press **Transmit All**.

   The analyzer displays “Transmitting All...” while the records are being sent.

Section 6

Calibration & Q. C.

6.1 Calibration

The piccolo xpress™ chemistry analyzer is self-calibrating. The bar code on the reagent disc contains the required information to perform its calibration when ever a reagent disc is run. Additionally, each reagent bead used in the disc is calibrated to a reference method and/or reference material. If the recommended procedures in the previous sections of this manual are followed, the analyte concentrations produced by the analyzer will be accurate.

6.2 Quality Control Features

The piccolo xpress™ includes quality control features such as optical sensing and electronic feedback systems, to ensure that accurate results are reported. The analyzer performs tests on both internal components and the reagent discs whenever the power is turned on and/or a reagent disc is inserted. Additionally, the analyzer continues to perform tests during analysis. Messages on the display or on the result printout warn of analyzer malfunctions and possible errors or explain why no results are reported.

1. Intelligent Quality Control (iQC)

   The piccolo xpress™ hardware performs an iQC test whenever power is turned on. iQC ensures that all optics, flash, and circuit board components are functioning properly and verifies the memory functions. The analyzer performs this analysis only when the iQC confirms that all components are functional. A hardware malfunction message appears on the display if any component malfunctions.

Statistical methods are incorporated into the analyzer software to ensure the accuracy of the results. The lamp flashes up to 13 time points for rate chemistries and typically three time points for endpoint chemistries. The distribution of flashes at each time point is analyzed and the standard deviation is compared to a pre-determined limit to ensure the analyzer is functioning properly.

2. Quality Control During Analysis

During an analysis, the analyzer's internal components and the reagent disc are checked to ensure the accuracy of the results.

a. piccolo xpress™ Analyzer

The analyzer's photometer takes readings with the light path obstructed and unobstructed to determine the appropriate light intensity range, and then checks that the range is within specification, before analysis begins. It also continually checks the performance of the motor, flash, and optics during analysis as well.

b. Reagent Disc

The analyzer performs several tests on the reagent disc during the analysis. These checks confirm:

- calibration factors
- expiration date
- all reagent beads are present
- timing of fluid movement through the disc
- diluent and sample mixing
- sufficient sample has been applied to the disc
- reagent beads dissolve when mixed with diluted sample

Each reagent disc contains reagents to detect exposure to extreme conditions such as temperature and humidity. The message "QC OK" is printed on the result printout when results from these reagents are within the expected ranges. Otherwise, no results are printed, and a "run canceled" message is shown on the display.

The analyzer monitors the performance of the reactions. For rate chemistries, the analyzer confirms that the reactions are linear with time, that the slope is within range, and whether the substrate has been depleted. In endpoint chemistries, the analyzer verifies the flatness (completeness) of the endpoints.

c. Sample

Samples are checked for physical interference. The analyzer estimates the sample indices, hemolysis, lipemia, and icterus using absorbance readings for the sample at 340 nm, 405 nm, and 467 nm. This information is then compared to pre-established limits for hemolysis, lipemia, and icterus for each method. When all three indices are below these limits for the method, the result for that method is printed on the result card. When even one index exceeds the limit, the result for the method is suppressed and the error condition displayed as HEM, LIP, or ICT.

6.3 Running External Controls

The Run Controls menu function (see Section 4.15) automatically stores control results in a memory separate from the patient results memory. The Recall function may be used to search for specific control results without searching through all patient results stored in memory.

Section 7

Troubleshooting

7.1 Error Messages

The analyzer can display warning and error messages when problems occur. These messages include an internal error code that will assist Abaxis Technical Support in diagnosing the problem. Record the error message and/or print an error report before calling Abaxis Technical Support at 800-822-2947.

7.2 Electrostatic Discharge

If the analyzer experiences an electrostatic discharge while running a sample, it may “freeze up.” If this happens, cancel the analysis (see page 3-10), then power the analyzer off and back on again. This should restore the analyzer to operating condition.

7.3 Technical Support

If the troubleshooting recommendations contained in this section do not correct the problem with the analyzer or the reagent discs, please contact Abaxis Technical Support:

- call 800-822-2947
- email technicalsupport@abaxis.com
- send a fax to 877-900-9333

7.4 Disc Cancellations

If the disc cancels, record the following information or print an error report and contact Abaxis Technical Support at 800-822-2947:

- Lot number
- Product name
- 4-digit error code
- Specimen type and sample

7.5 Instrument and Result Messages

The piccolo xpress™ chemistry analyzer performs a series of internal quality checks to ensure accurate results. When the analyzer detects a problem, the analyzer will either suppress certain chemistry results (~~~, HEM, LIP, or ICT printed in place of values) or cancel the run (disc cancels and no patient results printed). When either of these situations occur, the operator should proceed as follows:

Chemistry Suppression

Patient results print, but some results do not have numerical values.

The results printout includes troubleshooting "flags" — "HEM", "LIP", "ICT", or the symbols "~~~" — in place of values. Contact Abaxis Technical Support at 800-822-2947 to review the error report.

The error report can be printed using the Recall function starting from the Home screen. See Section 5.

Disc Cancellation

1. The display shows "Run Canceled" and no patient results are printed.
2. The display also shows an error code and a brief description of the error.
3. Record the error code.

Print an error report using the Recall function, which can be accessed from the Home screen. For details about printing error reports, see Section 5.

Symbols on the Results Printout

The following table explains the symbols that may appear on the results printout.

Symbols printed next to the result (see Section 3.3)		
Symbol	**Meaning**	**Notes**
*	The result is outside the reference range.	
<	The result is lower than the dynamic range.	To obtain more information for results with < or > printed before the value, print an error report (see Section 5). This report includes patient results, but the values are an approximation of the analyte concentration.
>	The result is higher than the dynamic range.	
H	After an LD value, indicates that hemolysis might affect the results.	
< *and* H	If < appears before and H after an LD result, hemolysis is more extensive (100–150 mg/dL) and the true LD value is less than reported.	
Symbols ("flags") printed instead of a result		
Symbol	**Meaning**	**Notes**
~~	Chemistry interference	
HEM	Hemolysis interference	
LIP	Lipemia interference	
ICT	Icterus interference	

The entire numerical line displayed on the error report, including the line HEM (H), LIP (L), and ICT (I), must be interpreted by a Technical Support Representative. Call Abaxis Technical Support at 800-822-2947.

7.6 Reinitializing the Analyzer

If the analyzer requires reinitialization, use the reinitialization function to return all settings to their original factory default values (including the clock), and also to clear all patient results, control results, and custom reference ranges from memory. Perform the following steps to reinitialize the analyzer.

1. In the Home screen, press the **Settings** icon.

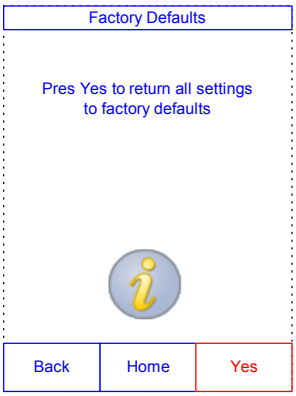
2. Press the **More Settings** icon.

3. Press the **Factory Settings** icon.

CAUTION: ***The next step is irreversible.*** *All settings — including custom reference ranges and the date and time —are returned to their factory values, and the memory is cleared. Results previously stored will not be recoverable.*

4. Press **YES** to restore all factory settings (including the clock) and to clear all memory from the analyzer.

   (Press the information icon for additional help.)



5. Refer to the sections noted below to reset the date and time, any custom reference ranges, and the units of measurement:

   - Section 4.2, “Customizing Reference Ranges,” on page 4-2
   - Section 4.7, “Changing Date and Time,” on page 4-18
   - Section 4.9, “Selecting Units,” on page 4-20

Section 8

Operating Principles

8.1 Principles of Procedure

The operator introduces a heparinized whole blood sample (or heparinized plasma, serum, or control) into the reagent disc. The reagent disc contains a diluent and test-specific reagent beads. The operator then places the disc in the piccolo xpress™ chemistry analyzer and enters the appropriate identification numbers. The analyzer automatically performs the remainder of the testing protocol.

The reagent disc spins and whole blood is separated into plasma and blood cells. During this time, the disc is heated to 37 ºC (98.6 ºF). Precisely measured quantities of plasma and diluent enter the mixing chamber and are mixed together. Through centrifugal and capillary forces, the diluted plasma is distributed to cuvettes on the perimeter of the disc. Reagent beads in the cuvettes are dissolved by the diluted plasma. This solution is thoroughly mixed and the resulting chemical reactions are monitored photometrically by the analyzer. Optical signals generated by the chemical reactions are used to calculate analyte concentrations. Calibration data specific for the chemistries in each disc are provided to the analyzer by the bar code printed on the bar code ring.

After the analysis is completed, the results print automatically. Analyte concentrations and reference ranges for each test in the panel and sample indices are included on a printout, providing a paper copy of the results. Results are also stored in the analyzer's memory and can be transmitted to external computers. The used reagent disc is removed and discarded. The piccolo xpress™ is then ready to analyze another sample.

8.2 Principles of Operation

Chemical reactions occur between reagent beads, the diluent contained in the reagent disc, and the added sample. These reactions produce chromophores that are measured photometrically by the piccolo xpress™. The microprocessor then calculates the concentrations of the analytes.

The measurement optics include a stroboscopic xenon lamp, a wavelength selection system, and a multiple-wavelength detector. Light from the lamp is directed by a mirror to pass through each cuvette. Some light is absorbed by the cuvette contents and the remainder travels through two apertures and is then collimated by a lens. Collimated light is split by beam splitters and interference filters at pre-determined wavelengths (340, 405, 467, 500, 515, 550, 600, 630, and 850 nm), and captured at each wavelength by photodiodes.

The chemical reactions utilized in the tests are designed to produce chromophores that absorb light at known wavelengths. The photometer measures light that is transmitted through a chromophore-containing cuvette (the reaction cuvette). The transmitted light, when corrected for flash-to-flash variability and electronic offset, is indirectly related to the analyte concentration of the sample. Transmittance measurements are converted to absorbance using the relationship: absorbance = –log (transmittance).

System errors and factors that may interfere with sample result calculations are eliminated by measuring light intensity at four locations of the reagent disc: the method-specific cuvette containing test reagent, sample, and diluent; the sample blank cuvette containing sample blank reagent, sample, and diluent (used in endpoint reactions, see below); the open cuvette, which allows all the light to pass through; and the dark cuvette, which blocks the passage of light.

Light passing through a reaction cuvette is measured both at the wavelength that is absorbed by the chromophore ($I_{\lambda 1RC}$) and at a wavelength not absorbed by the chromophore ($I_{\lambda 2RC}$). The ratio of these two measurements corrects for cuvette optical quality and flash-to-flash variability in the light source. The intensity of light transmitted through the open cuvette ($I_{\lambda 1OC}$, $I_{\lambda 2OC}$) is measured at the same two wavelengths as the light transmitted through the reaction cuvette. A correction for electronic offset is made at the same two wavelengths by measuring the residual signal when the dark cuvette is in the optical path ($I_{\lambda 10}$, $I_{\lambda 20}$).

The equation for calculating absorbance is:

$$A = -\log\left[\frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})}\right]$$

where:

A	= Absorbance at wavelength 1, referenced to wavelength 2
$I_{\lambda 1RC}$	= Intensity of light transmitted through the reaction cuvette at wavelength 1
$I_{\lambda 2RC}$	= Intensity of light transmitted through the reaction cuvette at wavelength 2
$I_{\lambda 1_0}$	= Intensity of light transmitted through the dark cuvette at wavelength 1
$I_{\lambda 2_0}$	= Intensity of light transmitted through the dark cuvette at wavelength 2
$I_{\lambda 1OC}$	= Intensity of light transmitted through the open cuvette at wavelength 1
$I_{\lambda 2OC}$	= Intensity of light transmitted through the open cuvette at wavelength 2

This is the basic equation to measure analyte concentrations in the rate methods and endpoint reactions used in chemistries.

Rate Methods

The rate of the reaction is calculated from the difference between absorbances measured at certain defined intervals on the linear portion of the reaction curve. Absorbances are taken throughout the read time to confirm the linearity of the reaction curve. The absorbance rates are converted to analyte concentrations by using the disc-specific calibration factors that are encoded on the bar code ring.

The equation for rate methods is:

$$\frac{\left\{-\log\left[\frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})}\right]_F\right\} - \left\{-\log\left[\frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})}\right]_B\right\}}{\text{Time Period}}$$

where:

$\Delta A/\Delta\tau$ = Rate of change of absorbance

F = Measurements taken at time F on linear portion of reaction curve

B = Measurements taken at time B on linear portion of reaction curve

t = Time in minutes

$I_{\lambda XX}$ = Other intensities, same as described above

Endpoint Reactions

Reagents, samples, and chromophores all absorb light in endpoint reactions. Light absorption by the samples must be subtracted so that the analyte concentration can be isolated. The absorbance of the sample is measured in a sample blank cuvette. Some chemistries employ a generic sample blank and others (such as total bilirubin) use a dedicated sample blank. The intensity of the light passing through the sample blank cuvette ($I_{\lambda 1SC}$, $I_{\lambda 2SC}$) is measured at the same wavelengths as is the light passing through the reaction cuvette.

The equation for endpoint reactions is:

$$A = -\log\left[\frac{(I_{\lambda 1RC} - I_{\lambda 1_0}) / (I_{\lambda 2RC} - I_{\lambda 2_0})}{(I_{\lambda 1OC} - I_{\lambda 1_0}) / (I_{\lambda 2OC} - I_{\lambda 2_0})}\right]$$

where:

$I_{\lambda 1SC}$ = Intensity of light transmitted through the sample blank cuvette at wavelength 1

$I_{\lambda 2SC}$ = Intensity of light transmitted through the sample blank cuvette at wavelength 2

$I_{\lambda XX}$ = Other intensities are the same as described above

The net absorbance is converted to analyte concentration using data encoded in the bar code printed on the bar code ring.

Section 9 Maintenance & Service

The piccolo xpress™ chemistry analyzer requires minimal maintenance. Clean the exterior of the analyzer weekly with mild detergent and a soft, damp cloth. The air filter requires cleaning twice per year. Regular maintenance of the analyzer will assure reliable operation.

CAUTION: *Abaxis recommends only the cleaning methods described in this section. If for some reason another method is needed, contact Abaxis Technical Support beforehand at 800-822-2947 to verify that the proposed method will not damage the analyzer. Abaxis is not responsible for damage caused by non-recommended cleaning methods.*

9.1 Cleaning the Analyzer

Clean the analyzer's external case and display at least weekly.

Cleaning the Case

Clean the analyzer with a soft cloth, dampened with a mild, non-abrasive detergent or cleaning solution, such as Simple Green®, a 10% bleach solution, or a 30% isopropyl alcohol solution. Pre-soaked towelettes (isopropyl alcohol) may be used as an alternate. Purchase isopropyl towelettes from computer retailers.

Do not spray or pour any detergents, solutions or other liquids directly onto the analyzer. Dampen a soft cloth or disposable paper towel with the detergent, then apply to the analyzer.

Cleaning the Display

Clean the analyzer's screen periodically using a soft, lint-free cloth dampened with a glass-cleaning fluid or window cleaner. The screen can be disinfected using a 10% bleach solution: apply the solution to a lint-free cloth, then wipe the screen.

CAUTION: *Do not use any cleaner containing alcohol. Do not spray cleaner directly onto the display — dampen the cloth instead.*

9.2 Cleaning Spills

Observe universal precautions[1] when cleaning spills on the analyzer. Use a 10% bleach solution (1 part bleach plus 9 parts water) to clean spills, following the standard cleaning guidelines in Section 9.1.

> ***Note:*** *For further guidelines on handling and disposing of hazardous laboratory wastes, refer to "Clinical Laboratory Waste Management; Approved Guideline—Second Edition" (GP5-A2), from the Clinical and Laboratory Standards Institute (formerly NCCLS). This can be found on the Internet at http://www.www.clsi.org.*

9.3 Cleaning the Air Filter

The air filter in the back of the analyzer should be cleaned at least twice per year. Check the air filter more often than twice per year if the analyzer is located in an environment with excessive dust or dirt.

To clean the air filter:

1. Unplug the analyzer and remove the power cord from the back of the analyzer.
2. Grasp the black mesh filter in the circular opening and remove it.
3. Wash the filter in warm soapy water and dry completely.
4. Place the clean, dry filter flat in the circular opening and push the sides of the filter behind the edges of the circular opening.
5. Plug the power cord into the back of the analyzer.
6. Plug the power cord into the power source, and press the Power button on the front of the analyzer. The analyzer will perform a diagnostic self test. It may take up to another four minutes for the heaters to bring the analyzer disc chamber to operating temperature.

Refer to Section 7, "Troubleshooting" if the analyzer does not successfully pass the self test. See Section 3.3 to run samples.

1. Clinical and Laboratory Standards Institute (formerly NCCLS). 2005. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—3rd Edition (M29-A3). Wayne, PA: CLSI; pp 29–31. Clinical and Laboratory Standards Institute (formerly NCCLS). 2002. Clinical Laboratory Waste Management; Approved Guideline—2nd Edition (GP5-A2). Wayne, PA: CLSI.

9.4 Updating the Analyzer Software

Software updates for the analyzer are provided by Abaxis to registered owners of the piccolo xpress™ chemistry analyzer, in CD-ROM format. Replacement software is mailed immediately whenever a new software version is released. See Section 4.6, "Viewing Analyzer Identification" to determine the software version installed in the analyzer. Contact Abaxis Technical Support immediately at 800-822-2947 if the software version is not the most recent release.

> ***Note:*** *Be sure to update the software every time an update CD is received from Abaxis.*

Update the analyzer software as follows:

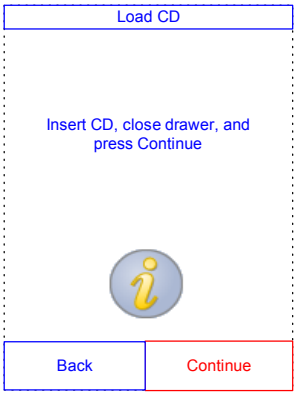
1. In the Home screen, press the **Settings** icon.

2. Press the **More Settings** icon.

3. Press the **Software Update** icon.

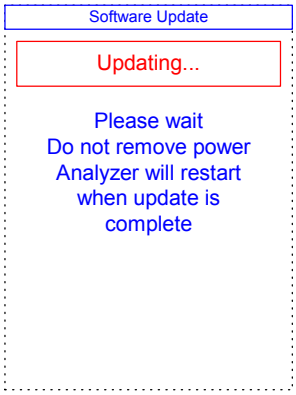
4. Place the CD in the drawer, press the drawer inward to close it, then press **Continue**.

   (Press the information icon for additional help.)



5. The software update then begins.

When the update is complete, the analyzer automatically shuts down and restarts.



CAUTION: *Do not remove the CD or remove power until after the analyzer shuts down and restarts to complete the software update, or you could damage the analyzer.*

9.5 Returning the Analyzer to the Manufacturer for Service

The piccolo xpress™ must be shipped in an authorized shipping container. Authorization for shipping and servicing the analyzer must be obtained from Abaxis Technical Support before sending the analyzer.

To obtain authorization for service on the analyzer, call Abaxis Technical Support at 800-822-2947.

Section 10

Connecting a Computer/Printer

10.1 Connecting an External Printer

You can print results from the piccolo xpress™ chemistry analyzer using any USB-compatible external printer approved by Abaxis. For a list of approved printers, call Abaxis Technical Support at 800-822-2947.

Connect and use the printer as described in the printer's instructions.

10.2 Connecting a Computer

The piccolo xpress™ analyzer is equipped to transmit patient and control results in multiple formats to a computer through the analyzer's USB serial port. To receive the results from the piccolo xpress™, the computer requires terminal emulation software (such as HyperTerminal, included with Windows 95 and higher) and driver software to communicate with the piccolo xpress™.

The results can be captured to a text file to be viewed with most word processing, spreadsheet, and database applications. This section describes the transmission specifications and hardware connections, and using HyperTerminal to capture results to a text file.

Note: *Data management systems can be interfaced with the piccolo xpress™ to collect analysis results. Since the installation for each type of data management system differs, please contact your data management system supplier for more information.*

10.3 Transmission Specifications

Cable	USB cable
Baud rate	9600
Data type	ASCII
Parity	None
Word length	8 bits
Stop bit	1
Start of transmission and new page sentinel	Form Feed (decimal 12 or hexadecimal 0C)
End of line sentinel	Carriage Return (decimal 13 or hexadecimal 0D) and Line Feed (decimal 10 or hexadecimal 0A)
End of transmission sentinel	End-of-File (decimal 26 or hexadecimal 1A)
Max number characters/line	30 (including Carriage Return and Line Feed)
Max number lines	26

Note: *The exact contents of the print card are transmitted. In some cases, the backlash (\ ) should be interpreted as the foreslash (/): for example, "mmo\L" is equivalent to "mmol/L" and "mmo\L" is "mmol/L" in the transmitted results.*

10.4 Installing the Abaxis® Driver

This section describes how to install a software driver that enables the piccolo xpress™ analyzer to communicate with a Windows, Linux, or Macintosh computer. The analyzer installs on the computer as a virtual communication port in the operating system.

Installing on a Windows PC

Installing the driver on a Windows PC requires the following:

- piccolo xpress™ analyzer
- PC with Windows 98, ME, 2000, or XP, and a USB port
- Type A/Type B USB cable
- Abaxis Driver CD

Note: *Driver installation in Windows 2000 or XP requires a user account with administrative privileges.*

The screenshots in these instructions are from a typical Windows XP Professional installation. Some of the items shown may vary slightly in other versions of Windows.

Note: *Do not connect the analyzer to the PC until instructed to do so.*

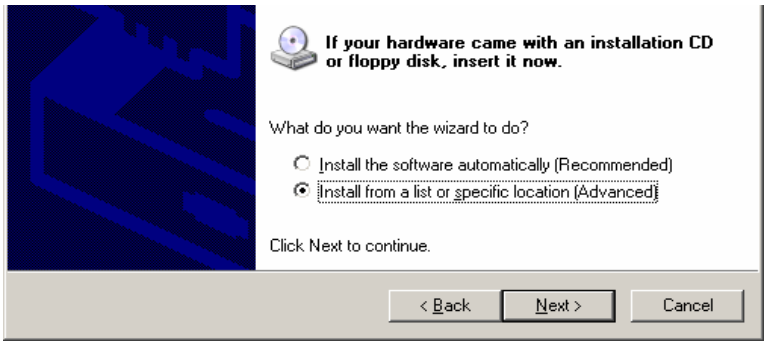
Install the driver as follows.

1. Turn on the PC, and insert the Abaxis Driver CD into the PC's CD-ROM drive.
2. Connect the USB cable to a Type A connector on the PC and to the uppermost USB connector (Type B) on the back of the analyzer.
3. Turn on the analyzer. Wait for the PC to recognize the analyzer and start the Found New Hardware Wizard — this may take a few minutes.

4. If the wizard asks to connect to Windows Update, select **No, not this time** and click **Next**.

Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Read our privacy policy
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

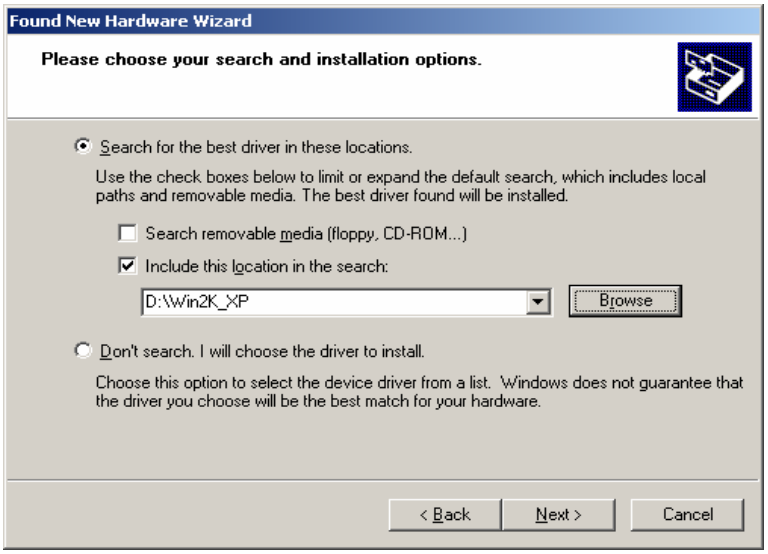
5. Select **Install from a list or specific location** and click **Next**.


If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

6. Select **Search for the best driver in these locations**, and check **Include this location in the search**.

7. Click **Browse**, then navigate to the PC's CD-ROM drive (with the Abaxis Driver CD).

8. On the drive, select the **Win2K_XP** folder for Windows 2000 or XP (as shown), or the **Win98_ME** folder for Windows 98 or ME, then click **Next**.


Found New Hardware Wizard
Please choose your search and installation options.
Search for the best driver in these locations.
Use the check boxes below to limit or expand the default search, which includes local paths and removable media. The best driver found will be installed.
Search removable media (floppy, CD-ROM...)
Include this location in the search:
D:\Win2K_XP
Browse
Don't search. I will choose the driver to install.
Choose this option to select the device driver from a list. Windows does not guarantee that the driver you choose will be the best match for your hardware.
< Back
Next >
Cancel

9. If warning appears stating that the software has not passed the Windows Logo testing, click **Continue Anyway**.

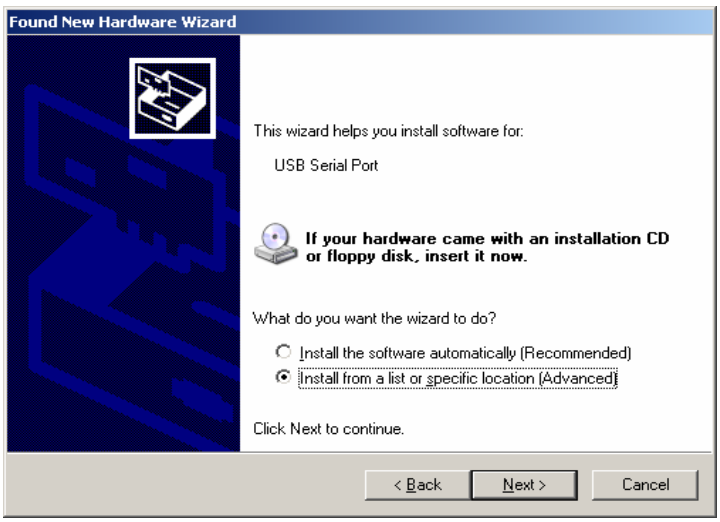
   The wizard then copies files from the CD onto the PC.

10. When this dialog appears, click **Finish**.

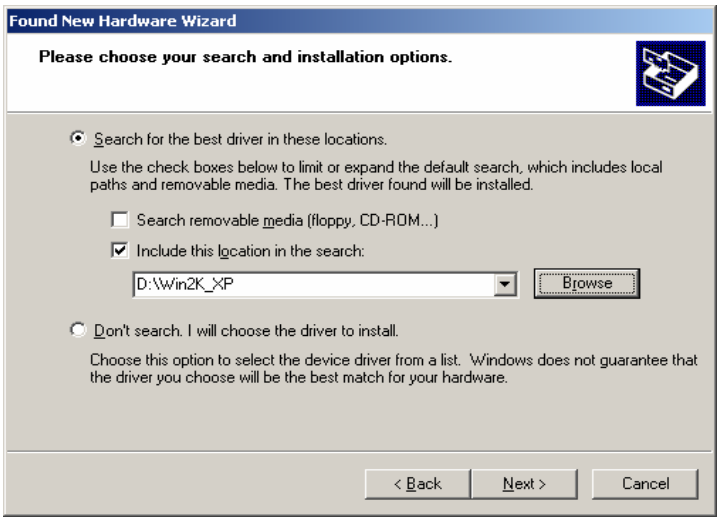
11. After a moment the wizard starts again. As before, if the wizard asks to connect to Windows Update, select **No, not this time** and click **Next**.

Found New Hardware Wizard
Welcome to the Found New Hardware Wizard
Windows will search for current and updated software by looking on your computer, on the hardware installation CD, or on the Windows Update Web site (with your permission).
Read our privacy policy
Can Windows connect to Windows Update to search for software?
Yes, this time only
Yes, now and every time I connect a device
No, not this time
Click Next to continue.
< Back
Next >
Cancel

12. Select **Install from a list or specific location** and click **Next**.


Found New Hardware Wizard
This wizard helps you install software for:
USB Serial Port
If your hardware came with an installation CD or floppy disk, insert it now.
What do you want the wizard to do?
Install the software automatically (Recommended)
Install from a list or specific location (Advanced)
Click Next to continue.
< Back
Next >
Cancel

13. Select **Search for the best driver in these locations**, and check **Include this location in the search**.


Found New Hardware Wizard
Please choose your search and installation options.
Search for the best driver in these locations.
Use the check boxes below to limit or expand the default search, which includes local paths and removable media. The best driver found will be installed.
Search removable media (floppy, CD-ROM...)
Include this location in the search:
D:\Win2K_XP
Browse
Don't search. I will choose the driver to install.
Choose this option to select the device driver from a list. Windows does not guarantee that the driver you choose will be the best match for your hardware.
< Back
Next >
Cancel

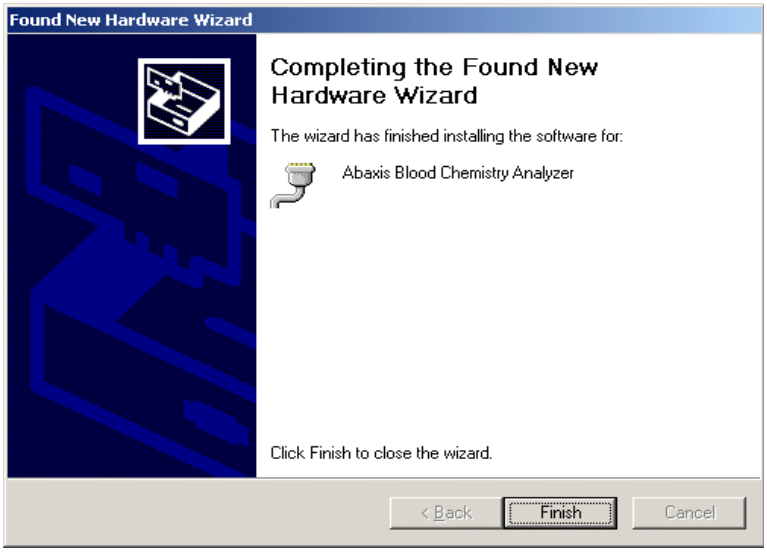
14. Click **Browse**, then navigate to the PC's CD-ROM drive (with the Abaxis Driver CD).

15. On the drive, select the **Win2K_XP** folder for Windows 2000 or XP (as shown), or the **Win98_ME** folder for Windows 98 or ME, then click **Next**.

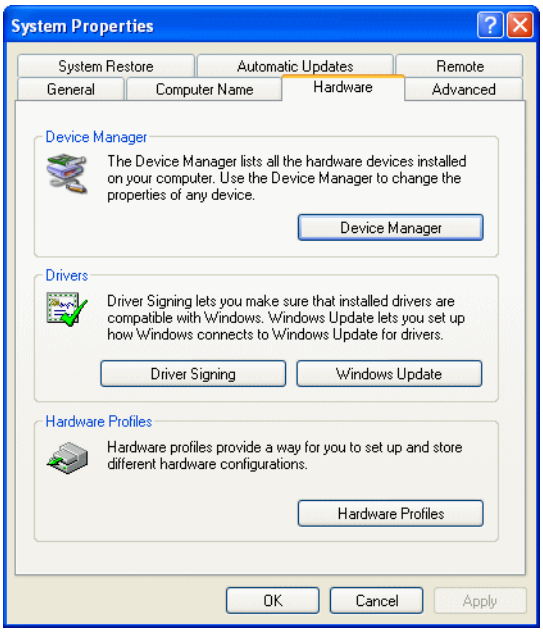
16. If warning appears stating that the software has not passed the Windows Logo testing, click **Continue Anyway**.

    The wizard then copies files from the CD onto the PC.

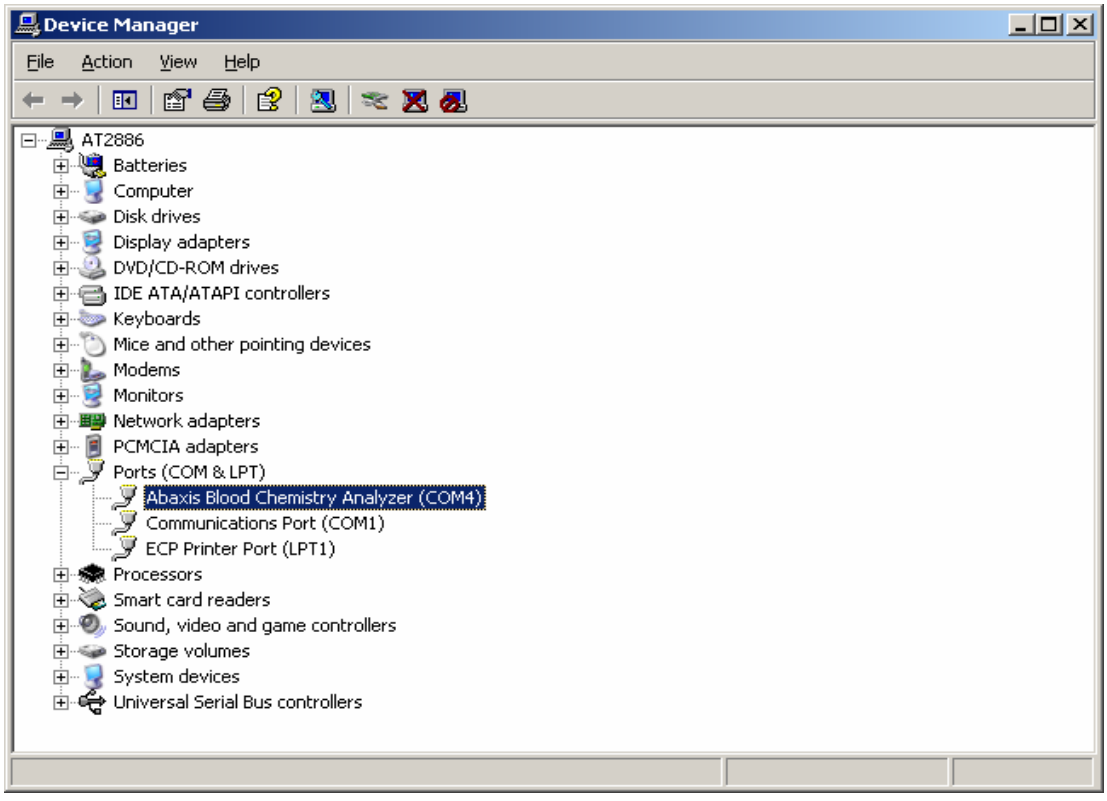
17. When this dialog appears, click **Finish**.


Found New Hardware Wizard
Completing the Found New Hardware Wizard
The wizard has finished installing the software for:
Abaxis Blood Chemistry Analyzer
Click Finish to close the wizard.
< Back
Finish
Cancel

18. Click **Start > Control Panel > Performance and Maintenance > System**, and click the **Hardware** tab.


System Properties
System Restore
Automatic Updates
Remote
General
Computer Name
Hardware
Advanced
Device Manager
The Device Manager lists all the hardware devices installed on your computer. Use the Device Manager to change the properties of any device.
Device Manager
Drivers
Driver Signing lets you make sure that installed drivers are compatible with Windows. Windows Update lets you set up how Windows connects to Windows Update for drivers.
Driver Signing
Windows Update
Hardware Profiles
Hardware profiles provide a way for you to set up and store different hardware configurations.
Hardware Profiles
OK
Cancel
Apply

19. Click **Device Manager**, then click the **+** before **Ports (COM & LPT)**. Note the port to which the analyzer was assigned.



Installing on a Linux PC

Connecting the piccolo xpress™ analyzer to a PC running the Linux operating system requires the following:

- piccolo xpress™ analyzer
- PC with Linux (kernel version 2.4 and above), and a USB port
- Type A/Type B USB cable

Note: *The driver is included in Linux kernel version 2.4 and above, but must be enabled to use.*

Enable the driver as follows:

1. Turn on the PC, and log in as "**root**."
2. Connect the USB cable to a Type A connector on the PC and to the uppermost USB connector (Type B) on the back of the analyzer.
3. Turn on the analyzer.
4. Open a terminal window on the PC, and enter the command "**modprobe ftdi_sio**" to enable the driver.
5. Configure any PC applications (such as minicom) to communicate with the analyzer over the virtual communication port (such as /dev/ttyS0).

Installing on a Macintosh Computer (OS X only)

Installing the driver on a Macintosh computer running system OS X requires the following:

- piccolo xpress™ analyzer
- Macintosh computer with Mac OS X, and a USB port
- Type A/Type B USB cable
- Abaxis Driver CD

Note: *Do not connect the analyzer to the Macintosh until instructed to do so.*

Install the driver as follows:

1. Turn on the computer, and insert the Abaxis Driver CD into the computer's CD-ROM drive.

2. In the Finder, go to the CD drive and run the driver installer:

   - ❑ For an Intel-based Macintosh: open the Mac\Intel folder and run the file FTDIUSBSerialDriver_vX_X_X.dmg.
   - ❑ For a PowerPC-based Macintosh: open the Mac\PPC folder and run the file FTDIUSBSerialDriver_vX_X_X.dmg.

3. Follow the instructions that appear on the screen, and restart the computer when prompted.

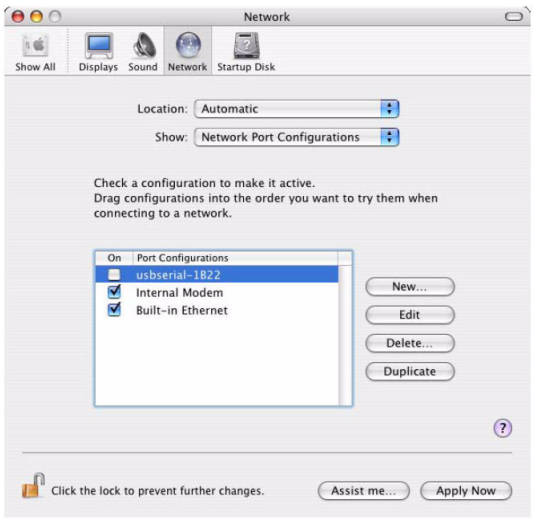
4. Connect the USB cable to a Type A connector on the computer and to the uppermost USB connector (Type B) on the back of the analyzer.

5. Turn on the analyzer.

6. Go to **Applications > System Preferences > Network** to enable the virtual communications port. Click **OK**.

New Port Detected
A new network port has been detected:
usbserial-1B22
Please verify that it is configured correctly, then press Apply Now to activate it.
OK

7. Select **Network Port Configurations** from the **Show** list. Enable the new port by checking the **On** box and clicking **Apply Now**.

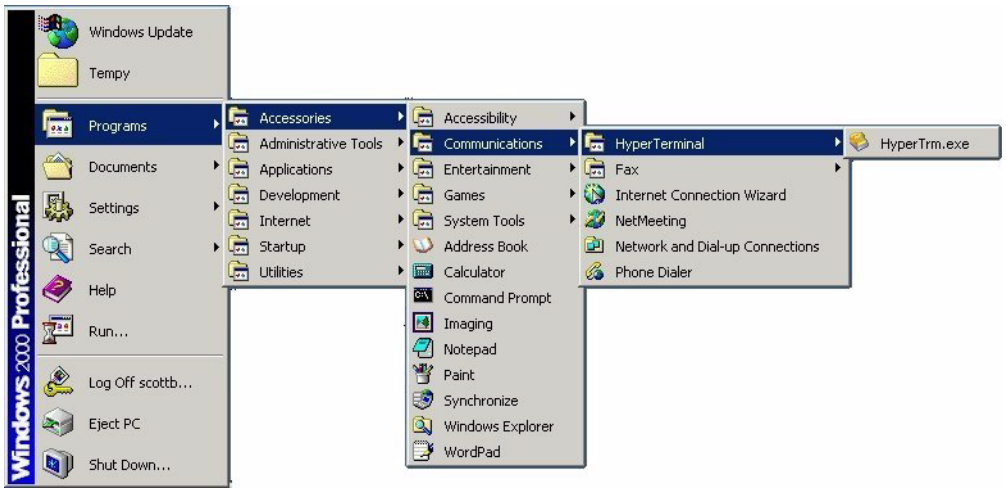


8. As needed, configure the computer's applications to communicate with the analyzer using the new virtual communication port.

10.5 Setting Up HyperTerminal

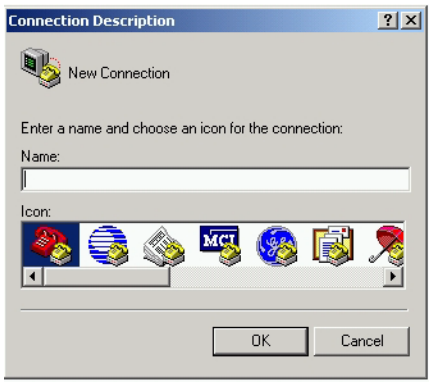
Note: *The screen captures and menu configurations shown below may vary slightly depending on your version of Windows.*

1. On the Windows desktop, select **Start > Programs > Accessories > Communications > HyperTerminal > HyperTrm.exe** to start the HyperTerminal setup wizard.



If HyperTerminal is not present, install it by going to **Start > Settings > Control Panel > Add/Remove Programs** (**Add/Remove Windows Components > Communications** tab). Please consult Windows documentation for details.

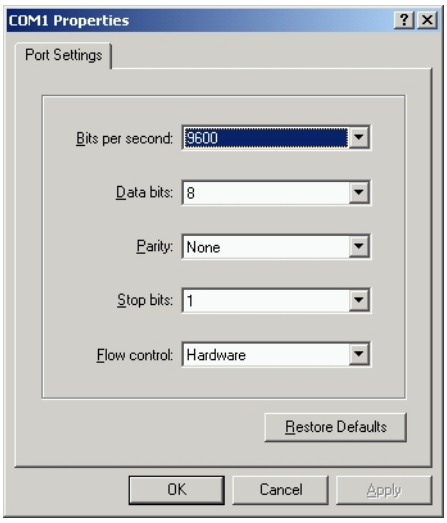
2. Type a descriptive name (e.g. Abaxis) for the connection in the **Name** box, then click **OK**.



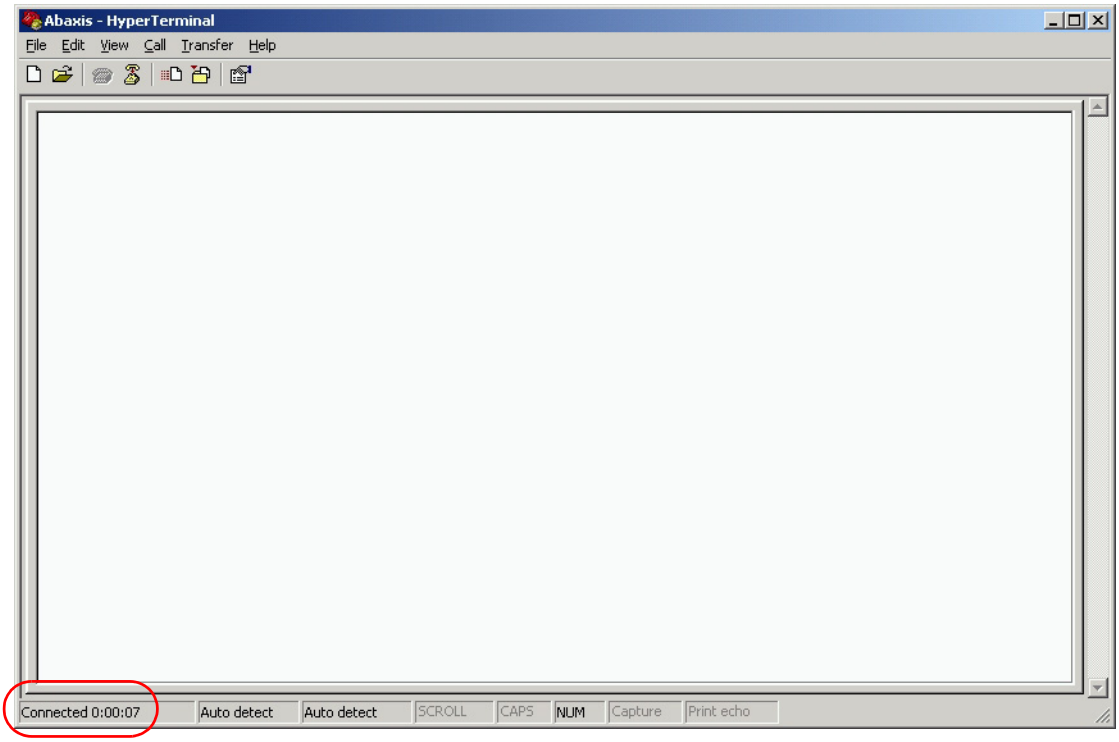
3. Select the port that the analyzer is connected to in the **Connect Using** box and click **OK**. The other settings are not required.

Note: *If the port is unknown, just select one for now. The wizard can be run multiple times to try different ports.*

4. Change the **Bits per second** to 9600 and click **OK**. Leave the other settings at their defaults.



5. If a valid port was selected, a new HyperTerminal session will start. The status pane on the lower left corner of the window should display “Connected” as shown below.



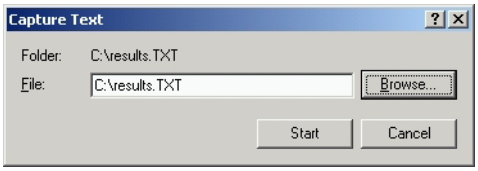
Note: *If an error message appears, close HyperTerminal (do not save changes). Run the HyperTerminal setup wizard again, and select a different port.*

6. Click **File > Save As** on the menu to save the HyperTerminal session. Note where the session file is saved so that it can be loaded in the future (create a shortcut on the desktop if necessary). Proceed to Section 10.6 for instructions on capturing results.

10.6 Capturing Results with HyperTerminal

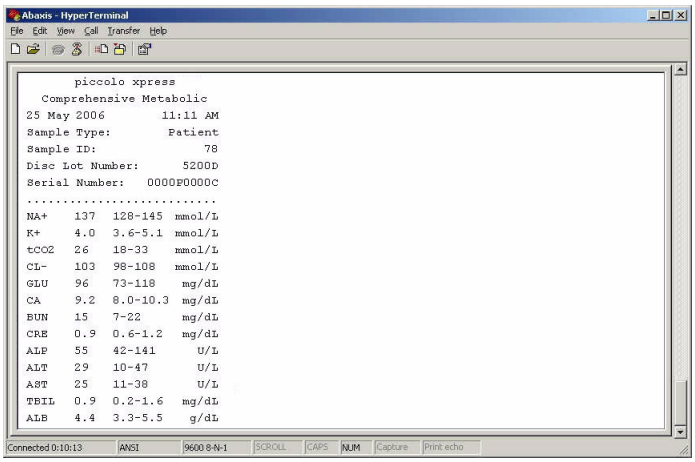
1. Prepare HyperTerminal to receive results by either loading a saved session file or creating a new session file as described in Section 10.5.

2. Click **Transfer > Capture Text** on the menu. Select a path and file name and click **Start**.



   Any results transmitted to the computer from this point forward will be captured to the designated text file.

3. Transmit results to the computer following the instructions in Section 4 and Section 5. The results will appear in the HyperTerminal window, as shown in this typical example. In addition to being captured to the text file, the results can be manually copied and pasted into other applications by highlighting the results and using the Edit menu.



   Note: *If the results do not appear in the HyperTerminal window it is possible that the incorrect port was selected in the setup steps (Section 10.5). Try repeating the setup steps and select a different port.*

4. After the desired number of results is transmitted, click **Transfer > Capture Text > Stop** from the menu. The captured text file can be interpreted by most word processing, spreadsheet, and database applications.

5. Close HyperTerminal by clicking **File > Exit** from the menu.

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